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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3781–3800

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*
WASHINGTON, D. C., *January 12, 1953.*

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*For presence of a habit-forming narcotic without warning statement, see No. 3782; contamination with filth, No. 3781; omission of, or unsatisfactory, ingredients statements, Nos. 3781, 3782; sale under name of another drug, No. 3785; failure to bear a label containing an accurate statement of the quantity of the contents, No. 3782; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 3782.

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NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3781. Adulteration and misbranding of Erbacidin tablets. U. S. v. 493 Vials. (F. D. C. No. 29328. Sample No. 38865–K.)

LIBEL FILED: May 18, 1950, District of Puerto Rico.

ALLEGED SHIPMENT: On or about January 31, 1950, by Carlo Erba, Inc., from New York, N. Y.

PRODUCT: 493 vials of *Erbacidin tablets* at San Juan, P. R. Analysis showed that a part of the acetylsalicylic acid in the tablets had undergone decomposition to form salicylic and acetic acids. Some of the tablets contained materially less than the declared amount of acetylsalicylic acid, and some of the tablets were broken and disintegrated.

LABEL, IN PART: (Vial) "25 Tablets Erbacidin Each Erbacidin tablet Contains: Pyranisamine maleate * * * Acetylsalicylic acid..... 0.1770 Gm."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

Adulteration, Section 501 (a) (1), the article consisted in part of a decomposed substance; and, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Acetylsalicylic acid . . . 0.1770 Gm." Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of the active ingredient, namely, salicylic acid. The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (e) (2), the label of the article failed to bear the common or usual name of the active ingredient, namely, aspirin. The article was misbranded in this respect when introduced into and while in interstate commerce.

DISPOSITION: July 14, 1950. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3782. Misbranding of dextro-amphetamine sulfate tablets, racemic amphetamine sulfate tablets, Seconal Sodium capsules, thyroid tablets, and diethylstilbestrol tablets. U. S. v. Allen Pearman (Pearman's Drug Store). Plea of guilty. Fine of $750, plus costs. (F. D. C. No. 31306. Sample Nos. 31167–L, 31168–L, 31285–L, 31290–L, 31936–L, 31937–L.)

INFORMATION FILED: February 27, 1952, Eastern District of Illinois, against H. Allen Pearman, trading as Pearman's Drug Store, Paris, Ill.

ALLEGED SHIPMENT: On or about May 8 and 9 and June 5, 1951, while a number of *dextro-amphetamine sulfate tablets*, *racemic amphetamine sulfate tablets*, *Seconal Sodium capsules*, *thyroid tablets*, and *diethylstilbestrol tablets* were being held for sale at Pearman's Drug Store after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the

contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *racemic amphetamine sulfate tablets* and *Seconal Sodium capsules* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and Section 502 (e) (1), the repackaged *racemic amphetamine sulfate tablets* and *diethylstilbestrol tablets* and a portion of the repackaged *dextro-amphetamine sulfate tablets* failed to bear labels containing the common or usual name of the drugs.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: September 18, 1952. A plea of guilty having been entered, the court imposed a fine of $750, plus costs.

3783. Misbranding of Mer-I-Col iron tonic. U. S. v. 58 Bottles * * * (and 4 other seizure actions). (F. D. C. Nos. 33193, 33210, 33212 to 33214, incl., 33218. Sample Nos. 1649–L, 2393–L, 2394–L, 4684–L, 4686–L, 4688–L, 7711–L.)

LIBELS FILED: On or about April 21, 28, and 29, and May 5, 1952, Western District of Pennsylvania, Northern and Middle Districts of Georgia, and Southern District of West Virginia.

ALLEGED SHIPMENT: On or about February 8, 11, 22, and 29, and March 6, 24, and 27, 1952, by the National Mer-I-Col Sales Co., from Columbus, Ohio.

PRODUCT: 706 8-ounce bottles and 222 16-ounce bottles of *Mer-I-Col iron tonic* at Bradford, Pa., Rome and Columbus, Ga., and Charleston and Huntington, W. Va.

RESULTS OF INVESTIGATION: Various representations concerning the conditions for which the product was intended were published in advertisements in local newspapers at the places where the product was located. These advertisements were printed on instructions of, and from mats furnished by, the National Mer-I-Col Sales Co.

LABEL, IN PART: (Bottle) "Mer-I-Col Iron Tonic * * * Active Ingredients Iron and Ammonium Citrates, Gentian Root, Thiamine Hydrochloride and a trace of Copper Sulfate (Iron Catalyst) Directions One tablespoonful before each meal, three times a day."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of rheumatism, arthritis, neuritis, stomach ailments, weak kidneys, rheumatic pains, nervousness, headaches, acids, toxins, bloating, weak back, lumbago, leg pains, lack of vitality and energy, poor appetite, underweight, dizzy spells, indigestion, stomach gas, dyspepsia, intense pain in stomach and chest, wild heart palpitation, fire-like feeling from the throat to the pit of the stomach, loss of weight, tissue, and strength, sour stomach, cramps, spitting up bits of half-digested food and hot, sour liquid, biliousness, sick headaches that last for days, constipation, yellowish complexion, painful, heavy, bloated feeling in the lower stomach, worn-out feeling, sleeplessness, neuralgia, sharp pain over kidneys,

aching back, stiffness in back and lower limbs, frequent rising at night, spots before the eyes, swelling of ankles, feet, and lower limbs, puffs or dark circles underneath the eyes, atonic constipation, spastic constipation, and pains in the arms, shoulders, fingers, hands, back, wrists, hips, knees, calves, thighs, feet, ankles, and neck, which were the conditions for which the article was intended. The article was misbranded in the above respect when introduced into and while in interstate commerce.

Further misbranding Section 502 (a), the labeling of the portion of the product at Columbus, Ga., namely, a clipping which was from a local newspaper and which accompanied the article, was false and misleading. The labeling contained statements which represented and suggested that the article was an effective treatment for the conditions referred to above. The article was not effective for such purposes. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: Between May 15 and August 22, 1952. Default decrees of condemnation and destruction.

3784. Misbranding of herb preparations. U. S. v. 29 Bottles, etc. (F. D. C. No. 33201. Sample Nos. 8970–L to 8975–L., incl.)

LIBEL FILED: On or about April 29, 1952, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about November 24, 1950, and February 26, April 24, May 25, and June 13, 1951, by the Indiana Botanic Gardens, from Hammond, Ind.

PRODUCT: 29 bottles of *Old Chief's prostate treatment*, 13 bottles of *Old Chief's nerve special*, 26 cartons of *Old Chief's Indian gall bladder herb tea*, 10 cartons of *Old Chief's Indian high blood pressure herb tea*, 6 cartons of *Old Chief's Indian reducing obesity herbs*, and 10 packages of *Old Chief's Indian laxative herb tea* at Detroit, Mich., in possession of the Old Chief Medicine Co.

RESULTS OF INVESTIGATION: The products were shipped in bulk and were repackaged and relabeled by the consignee.

LABEL, IN PART: (Bottles) "The Old Chief's Prostate Treatment * * * Active Ingredients: An Infusion of Palmetto Berries, Damiana, Juniper Berries, Bearberry Leaves, Corn Silk, Althea. Contents: 16 fl. ounces" and "The Old Chief's Nerve Special Active Ingredients: Valerian Root, Lady Slipper, Black Cohosh, Skunk Cabbage, Catnip, Hops, Black Haw, Alcohol 10 percent."

(Cartons) "Old Chief's Indian Gall Bladder Herb Tea * * * Active Ingredients: Wallwort, Flaxseed, Boneset, Buckthorn, Marshmallow. Contents: 8 Oz. Adv.," "Old Chief's Indian High Blood Pressure Herb Tea * * * Active Ingredients: Mistletoe, Marshmallow, Sassafras, Licorice. Contents: 8 Oz. Adv.," "Old Chief's Indian Reducing Obesity Herbs * * * Active Ingredients: Sassafras, Elder Flowers, Rosemary, Chickweed, Horsetail Grass, Poke Root, Yerba Santa, Juniper, and Licorice," and "Old Chief's Indian Laxative Herb Tea * * * Active Ingredients: Buckthorn, Licorice, Senna Sagrada, Senna Tinnevilly, and Cascara Alexandria. Contents: 7 Oz., Adv."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the labels of the articles were false and misleading since the articles were not effective for the purposes and conditions stated and implied and since frequent or continued use of *Old Chief's Indian laxative herb tea* was capable of establishing dependence upon laxatives to move the bowels: (29-bottle lot) "Prostate Treatment This preparation * * * used for Prostate weakness. Increases the functional activity"; (13-bottle lot) "Nerve Special"; (26-carton

lot) "Gall Bladder Herb Tea * * * It has restored health to thousands * * * The Way To Health * * * effectiveness in giving relief and in remedying ailments * * * They are of great benefit in the ailments for which they are recommended. They are reliable * * *"; (10-carton lot) "High Blood Pressure Herb Tea * * * It has restored health to thousands * * * The Way To Health * * * effectiveness in giving relief and in remedying ailments. * * * They are of great benefit in the ailments for which they are recommended. They are reliable * * *"; (6-carton lot) "Reducing Obestity Herbs * * * It has proven valuable to thousands. * * * This is a saline * * * very effective in correcting overweight. * * * The Way to Health * * *"; and (10-package lot) "The herbs used in this combination * * * have no habit forming effects. It has restored health to thousands. * * * used for chronic constipation of long standing conditions. * * * The Way To Health * * * effectiveness in giving relief and in remedying ailments * * *."

Further misbranding, Section 502 (f) (2), the labeling of the *Old Chief's Indian laxative herb tea* failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe duration of administration, in such manner and form, as are necessary for the protection of users, since it failed to bear a warning to the effect that the article should not be taken in case of acute abdominal pains, nausea, vomiting, or other symptoms of appendicitis, and that frequent or continued use of the article may result in dependence upon laxatives to move the bowels.

The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the articles other than the *Old Chief's Indian laxative herb tea* failed to bear adequate directions for use since it failed to state the purposes for which the articles were to be taken. These articles were misbranded in this respect when introduced into and while in interstate commerce.

DISPOSITION: June 5, 1952. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3785. Adulteration and misbranding of cortisone acetate tablets. U. S. v. Albert Feldman (Calvert Chemists). Plea of nolo contendere. Issue raised as to matters which the court could consider in imposing sentence. Court ruled willfullness or intentional wrongdoing not alleged in the information cannot be considered by court in imposing sentence on plea of nolo contendere. Defendant fined $500, given suspended sentence of one year in prison, and placed on probation for one year. (F. D. C. No. 31261. Sample Nos. 2962–L, 2963–L, 2966–L to 2968–L, incl., et al.)

INFORMATION FILED: December 27, 1951, District of Columbia, against Albert Feldman, trading as Calvert Chemists, Washington, D. C.

ALLEGED VIOLATION: On or about March 15, 17, 19, and 24, 1951, in response to prescriptions surrendered to the defendant for filling, calling for a number of compound tablets containing 25 milligrams of cortisone acetate, the defendant dispensed a number of tablets of a drug containing ascorbic acid, and by

*See also No. 3781.

such act caused the drug so dispensed to be adulterated and misbranded in interstate commerce.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance, namely, ascorbic acid had been substituted for cortisone acetate.

Misbranding, Section 502 (a), the label on the bottles in which the drug was dispensed contained statements which represented and suggested that the article contained in the bottles was cortisone acetate, which statements were false and misleading since the article contained in the bottles was ascorbic acid; and, Section 502 (i) (3), the article contained in the bottles was offered for sale under the name of another drug, namely, cortisone acetate.

DISPOSITION: On January 29, 1952, a plea of nolo contendere was entered by the defendant, after which the case was referred to the probation officer. Thereafter a dispute developed as to whether the defendant in filling the prescriptions referred to in the information, intentionally or mistakenly substituted another drug for the one prescribed. The matter was referred to the court, and on March 10, 1952, the following decision was handed down:

LAWS, *Chief Judge:* "On the recommendation of the District Attorney the Court accepted a plea of nolo contendere in the above-entitled case in which the defendant is charged with selling adulterated and misbranded drugs in violation of Title 21, Sections 331 (b) and 333 (a) United States Code. The information to which defendant pleaded charges a misdemeanor which does not require elements of willfulness or of any intentional wrongdoing. There is another section of the same statute under which the information against the defendant was filed which provides that if the acts charged against defendant were done with intent to defraud or mislead, the accused shall be guilty of a felony. No charge is brought against the defendant under this section. In submitting this case to the probation officer after accepting defendant's plea of nolo contendere to a charge not involving willfulness or intentional wrongdoing, the Government has taken the position that defendant has been guilty of willful acts. The defendant, on the other hand, has denied any such acts.

"The Court is definitely of the opinion that on a plea of nolo contendere to an offense which does not involve willfulness or intentional wrongdoing, it cannot take into consideration either willfulness or intentional wrongdoing. This would be true in any case, but is especially true where a part of the same statute provides a separate crime in the event of willfulness and intentional wrongdoing.

"Of course the Court will take into account the fact that the defendant has pleaded nolo contendere to repeated violations of the charge pending against him and to the extent this shows culpability, the Court will consider it. However, on the present state of the record, the Court is not in position to impose a sentence for willful and intentional wrongdoing.

"Counsel for defendant has made it plain that defendant does not wish to withdraw his plea of nolo contendere. The District Attorney has indicated that under certain conditions, depending upon the view of the Court as to its power to consider claims of willful and intentional wrongdoing, he might wish to have the plea withdrawn. Now that the Court has made clear its view as to the limitations on the evidence it may consider in imposing sentence, the District Attorney is requested to advise the Court definitely whether he wishes the plea to nolo contendere withdrawn and the case set down for trial."

Following the above decision, an indictment was returned against the defendant relating to the same acts alleged in the information, but charging intent to defraud and mislead. Subsequently, the Government and the defendant stipulated that the court might hear evidence as to whether or not the defendant acted willfully and intentionally. In accordance with such stipulation, the matter came on for hearing in open court on June 10, 1952, and at the conclusion of the hearing the matter was taken under advisement

by the court. On June 27, 1952, the court handed down the following memorandum:

MEMORANDUM ON IMPOSITION OF SENTENCE

LAWS, *Chief Judge:* "On December 27, 1951, an information was filed against defendant charging him with misdemeanors, consisting of misbranding and adulterating drugs on five different occasions between March 15 and March 24, 1951. On each instance it was claimed defendant substituted inexpensive ascorbic acid pills for cortisone pills, which were both rare and expensive. The charge made no reference to willful wrongdoing. On January 29, 1952, before the date set for trial of the case, defendant appeared before the Court with his counsel and an Assistant United States Attorney. The latter informed the Court that the defendant wished to enter a plea of *nolo contendere* and that this disposition was satisfactory to the prosecution. Relying upon this statement, the Court accepted the plea. Such a plea is regarded as of less significance than a plea of guilty and is properly used only in offenses implying little or no moral dereliction. A widely accepted definition of the plea refers to it as 'An implied confession * * * where, in a case not capital, a defendant does not directly own himself to be guilty, but tacitly admits it by throwing himself on the King's mercy, and desiring to submit to a small fine, which the court may either accept or decline, as they think proper.' *1 Chitty, Criminal Law, 1819 ed., c. 10, p. 430.*

"During pre-sentence investigation by the Court's Probation Officer, it became known for the first time that the prosecution claimed guilt of willful wrongdoing. When informed of this, the Court called the prosecutor and counsel for defendant to a conference in chambers. It was then made clear that the Court would not impose sentence for willful acts upon an information not charging willfulness, especially in a case such as this in which the statute provided a separate and far more serious offense for willful and intentional wrongdoing. On March 10, 1952, the Court, in a written memorandum, confirmed its position in this regard, and stated that if the District Attorney wished to have the plea of *nolo contendere* withdrawn, he should so advise the Court. No request to have the plea withdrawn was made. But on April 28, 1952, the Grand Jury filed an indictment against the defendant covering the same transactions as the information, but charging intent to defraud and to mislead.

"Notwithstanding the Court's unequivocal statement that in sentencing defendant on his plea of *nolo contendere* to the information, it would not consider willful or intentional acts charged in the indictment, as to which no guilt had been established, the prosecution and defendant stipulated that the Court might hear evidence as to whether or not the defendant acted willfully and intentionally. Pursuant to this stipulation, both parties adduced such evidence in open court. While hearing this evidence, the Court asked whether the parties had stipulated, or were willing to stipulate, that it might make a decision as to defendant's guilt or innocence of intentional wrongdoing. While the Assistant District Attorney expressed his willingness to so stipulate, counsel for defendant announced he did not so stipulate and did not wish to do so. Thus the Court was called on to hear, at some length, evidence as to guilt or innocence on an untried indictment, without any right to deal with that evidence.

"The Court knows of no precedent for the unusual procedure followed in this case. It is one which should not be sanctioned. If the prosecution relies on willful misconduct, which defendant denies, it should charge it and prove it at a regular trial in accordance with established procedures. Here it is suggested that the Court consider alleged willful acts, when guilt of those acts has neither been admitted nor proved and when the Court has no legal right to determine guilt or innocence.

"The Court has considered the cases cited by the Government in support of the procedure followed in this case. At most, they hold that the Court in imposing sentence, may consider a wide area of collateral factors, such as environmental background, past record, and aggravating or mitigating circumstances incidental to the offense for which sentence is to be imposed. It does not follow the Court may impose sentence upon the basis of evidence tending to show that the offense for which defendant is to be sentenced was

merely an incident of a much greater offense as to which there has been neither a plea of guilty nor a trial.

"Defendant has had a good reputation. Leading citizens have testified to this. But it is apparent he was culpable in respect of his filling of at least five prescriptions for an important and rare drug. There is obligation on a druggist to exercise extreme care in filling prescriptions. Cortisone was scarce and expensive. It was supplied from small bottles. The substituted drug, while similar in appearance to cortisone, was inexpensive and supplied from large bottles. In this case the drug furnished was not harmful, and, as stated, the Court cannot consider claims that the substitution was willful. However, lack of a needed prescription may prove disastrous, and culpable acts may be quite as injurious as intentional acts. Defendant's acts on the different occasions (he has no explanation other than conjecture as to how it happened) cannot be treated lightly. Since the Court on the present record may and does not find intentional wrongdoing or any moral turpitude on defendant's part but is dealing only with an uncontested charge of culpability, it will not require defendant to serve a term of imprisonment."

Immediately thereafter, on June 27, 1952, the court fined the defendant $500, imposed a suspended sentence of 1 year in prison, and placed him on probation for 1 year. On July 2, 1952, the indictment against the defendant was dismissed on motion of the Government.

3786. Adulteration and misbranding of phenobarbital and atropine sulfate tablets, pentobarbital sodium capsules, phenobarbital tablets, thyroid tablets, and phenacetin tablets. U. S. v. Cowley Pharmaceuticals, Inc., and Ben C. Cowley. Pleas of guilty. Fine of $500 against corporation and fine of $100 against individual. (F. D. C. No. 32741. Sample Nos. 4810–L, 4815–L, 5355–L, 22833–L, 22836–L.)

INFORMATION FILED: May 8, 1952, District of Massachusetts, against Cowley Pharmaceuticals, Inc., Worcester, Mass., and Ben C. Cowley, president and treasurer of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of November 24, 1950, and April 24, 1951, from the State of Massachusetts into the States of Vermont, New Hampshire, and New York.

NATURE OF CHARGE: *Phenobarbital and atropine sulfate tablets.* Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess in that it was represented to contain ¼ grain phenobarbital per tablet, whereas it contained less than ¼ grain of phenobarbital per tablet. Misbranding, Section 502 (a), the label statement "Each tablet contains: Phenobarbital USP ¼ gr." was false and misleading.

Pentobarbital sodium capsules. Adulteration, Section 501 (b), the article was represented as "Pentobarbital Sodium Capsules," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard in that it contained less than 90 percent of the labeled amount of sodium pentobarbital, the minimum permitted by the standard. Misbranding, Section 502 (a), the label statement "Capsules Sodium Pentobarbital * * * 100 mgs. (1½ gr.)" was false and misleading since each capsule of the article contained less than 100 mg. (1½ grs.) of pentobarbital sodium.

Phenobarbital tablets. Adulteration, Section 501 (b), the article was represented as *phenobarbital tablets*, a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since it contained less than 94 percent of the labeled amount of phenobarbital, the minimum permitted by the standard. Mis-

branding, Section 502 (a), the label statement "Tablets Phenobarbital USP 1 Grain" was false and misleading since it represented and suggested that each tablet conformed to the requirements for *phenobarbital tablets* as specified in the United States Pharmacopeia, whereas each tablet did not conform to such requirements since each tablet contained less than 94 percent of the labeled amount of phenobarbital, the minimum permitted by the Pharmacopeia.

Thyroid tablets. Adulteration, Secton 501 (b), the article was represented as "Thyroid Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard in that the article contained an amount of iodine (I) in thyroid combination equivalent to less than 0.17 percent of the labeled amount of thyroid, the minimum permitted by the standard. Misbranding, Section 502 (a), the label statement "Tablets Thyroid USP, 1 Gr." was false and misleading since it represented and suggested that each tablet of the article conformed to the requirements for *thyroid tablets* as specified in the United States Pharmacopeia, whereas each tablet of the article did not conform to such requirement since each tablet contained an amount of iodine (I) in thyroid combination equivalent to less than 0.17 percent of the labeled amount of thyroid.

Phenacetin tablets. Adulteration, Section 501 (b), the article was represented as a drug, the name of which (acetophenetidin tablets) is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since it contained less than 94 percent of the labeled amount of acetophenetidin, the minimum permitted by the standard. Misbranding, Section 502 (a), the label statement "Tablets Phenacetin USP., 5 Grains" was false and misleading since it represented and suggested that each tablet of the article conformed to the requirements for acetophenetidin tablets as specified in the United States Pharmacopeia, whereas each tablet did not conform to such requirements since each tablet contained less than 94 percent of the labeled amount of acetophenetidin.

DISPOSITION: June 25, 1952. Pleas of guilty having been entered, the court ordered that a fine of $500 be imposed against the corporation and that a fine of $100 be imposed against the individual.

3787. Adulteration of epinephrine hydrochloride injection. U. S. v. Wilson & Co., Inc., (Wilson Laboratories, Div. of Wilson & Co., Inc.). Plea of nolo contendere. Fine, $500. (F. D. C. No. 33713. Sample Nos. 24922-L, 36640-L.)

INFORMATION FILED: August 28, 1952, Northern District of Illinois, against Wilson & Co., Inc., trading at Chicago, Ill., under the name of the Wilson Laboratories, Div. of Wilson & Co., Inc.

ALLEGED SHIPMENT: On or about September 2, 1949, from the State of Illinois into the State of Indiana.

PRODUCT: The product was invoiced as "Epinephrine Hydrochloride *Injection* 1-1000." Two samples were collected from the shipment involved, and analysis disclosed that one of the samples possessed a potency of not less than 240.2 plus or minus 5.26 percent, and that the other sample possessed a potency of 425.5 plus or minus 12.6 percent, of the declared potency.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a product having a potency equivalent to that of a solution containing more than 1 gram of U. S. P. Epinephrine Reference Standard per 1,000 cc. had been substituted for

a product having a potency equivalent to a solution containing 1 gram of U. S. P. Epinephrine Reference Standard per 1,000 cc., which the product purported and was represented to be.

DISPOSITION: September 22, 1952. A plea of nolo contendere having been entered, the court imposed a fine of $500.

3788. Adulteration of grindelia. U. S. v. 18 Bales * * *. (F. D. C. No. 32238. Sample No. 28573–L.)

LIBEL FILED: December 18, 1951, District of New Jersey.

ALLEGED SHIPMENT: By J. G. Olvey and Associates from Colusa, Calif.

PRODUCT: 18 225-pound bales of *grindelia* at Jersey City, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as *grindelia*, a drug the name of which is recognized in the National Formulary, an official compendium, and its quality fell below the official standard since the article contained more than 10 percent of stems over 2 mm. in diameter, the maximum permitted by the standard.

DISPOSITION: June 26, 1952. S. B. Penick & Co., Jersey City, N. J., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

3789. Adulteration and misbranding of Uni-Swabs. U. S. v. 126 Packages * * * (and 1 other seizure action). (F. D. C. Nos. 33278, 33384. Sample Nos. 6731–L, 8449–L.)

LIBELS FILED: May 27 and June 5, 1952, District of Massachusetts and Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 21 and April 2, 1952, from Jamaica and Hollis, N. Y.

PRODUCT: *Uni-Swabs.* 250 packages, each containing 200 swabs, and 40 packages, each containing 80 swabs, at Leominster, Mass., and Erie, Pa.

LABEL, IN PART: "Uni-Swabs 200 [or "80"] Individual Swabs in Cellophane Packets Sterile when Packed."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, namely, "Sterile when Packed."

Misbranding, Section 502 (a), the label statement "Sterile when Packed" was false and misleading since the article was not sterile when packed, but was contaminated with living micro-organisms.

DISPOSITION: July 21, 1952. Default decrees of condemnation. The court ordered that the Massachusetts lot be destroyed and that the Pennsylvania lot be delivered to a hospital on condition that it be sterilized before using.

3790. Adulteration and misbranding of Uni-Swabs. U. S. v. 12 Dozen Boxes * * *. (F. D. C. No. 33268. Sample No. 37805–L.)

LIBEL FILED: May 22, 1952, District of New Jersey.

ALLEGED SHIPMENT: On or about April 11, 1952, by Steri-Swabs, Inc., from Hollis, Long Island, N. Y.

PRODUCT: 12 dozen boxes of *Uni-Swabs* at Newark, N. J. The articles consisted of pledgets of absorbent cotton on sticks.

LABEL, IN PART: (Box) "Uni-Swabs 80 Individual Swabs in Cellophane Packets Sterile when Packed."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, namely, "Sterile when Packed."

Misbranding, Section 502 (a), the label statement "Sterile when Packed" was false and misleading as applied to an article which was not sterile when packed but which was contaminated with living micro-organisms.

DISPOSITION: July 11, 1952. Default decree of condemnation and destruction.

3791. Adulteration and misbranding of adhesive bandages. U. S. v. 40 Cartons * * *. (F. D. C. No. 33298. Sample No. 37808–L.)

LIBEL FILED: June 17, 1952, District of New Jersey.

ALLEGED SHIPMENT: On or about April 21, 1952, by American White Cross Labs., Inc., from New Rochelle, N. Y.

PRODUCT: 40 cartons, each containing 12 boxes, of *adhesive bandages* at Newark, N. J.

LABEL, IN PART: (Carton) "One Dozen American White Cross Waterproof Adhesive Bandages Ten's Mercurochrome Pad"; (box) "American White Cross Sterile Waterproof 10 Adhesive Bandages."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard in that it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterile" was false and misleading.

DISPOSITION: August 8, 1952. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3792. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. 43,000 Tablets * * *. (F. D. C. No. 33103. Sample No. 12723–L.)

LIBEL FILED: April 28, 1952, Northern District of Ohio.

ALLEGED SHIPMENT: On or about February 11, 1952, by the Robin Pharmacal Corp., from Brooklyn, N. Y.

PRODUCT: 43,000 *dextro-amphetamine sulfate tablets* at Cleveland, Ohio. Analysis showed that the product was racemic amphetamine sulfate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Dextro-Amphetamine Sulfate" was false and misleading as applied to the article, which was racemic amphetamine sulfate.

DISPOSITION: May 23, 1952. Default decree of condemnation and destruction.

3793. Misbranding of Nutrient tablets, Inorganic Nutrient tablets, soyabean oil, and soya lecithin. U. S. v. 1 Bottle, etc. (F. D. C. No. 31398. Sample Nos. 23455–L, 23456–L, 23458–L, 23459–L.)

LIBEL FILED: August 9, 1951, Northern District of New York.

*See also Nos. 3783–3786, 3789–3791.

ALLEGED SHIPMENT: On or about May 19, June 11 and 25, and July 3, 1951, by Inorganic Bioelements, Inc., from Cleveland, Ohio.

PRODUCT: 2 60-tablet bottles of *Nutrient tablets*, 1 500-tablet bottle and 5 60-tablet bottles of *Inorganic Nutrient tablets*, 10 1-pint bottles of *soyabean oil*, and 5 8-ounce bottles of *soya lecithin* at Binghamton, N. Y.

LABEL, IN PART: (Bottle) "Inorganic Nutrient Tablets * * * Each tablet contains 170 mg. Manganese Sulfate, 1 mg. Copper Sulfate, 3 mg. Cobalt Sulfate, 1 mg. Zinc Sulfate, 10 mg. Iron Sulfate in combination with Lecithin * * * Directions Adults: 2 tablets daily * * * Children (10–16 years): one tablet daily," "Nutrient Tablets (Multiple Trace Elements containing Manganese in the organic form of an Amino Acid Salt.) Each tablet contains: 155 mg. Manganese Glutamate, 1 mg. Copper Sulfate, 3 mg. Cobalt Sulfate, 1 mg. Zinc Sulfate, 10 mg. Iron Sulfate in combination with Lecithin. * * * Directions Adults: 2 tablets daily * * * Children (10–16 years): one tablet daily," "One Pint Soyabean Oil," and "Soya Lecithin, Refined Edible, Oil Free * * * 8 Ounces Net."

NATURE OF CHARGE: *Nutrient tablets* and *Inorganic Nutrient tablets.* Misbranding, Section 502 (a), certain statements on the bottle labels and in booklets and leaflets accompanying the articles, namely, "Notes on Inorganic Bioelements," "Retail Price List," "Brucellosis and Mastitis," "Inorganic Bioelements in Nutrition," "Health vs. Disease," and "Bangs Disease and Undulant Fever are due to Nutritional Deficiencies," were false and misleading. The statements represented and suggested that the articles were effective to correct deficiencies of the relative essential elements and their consequences; that manganese, cobalt, and zinc play an essential role in nutrition and body functions, and that an insufficient quantity of such elements in the food supply will lead to so-called deficiency diseases and invite the invasion of disease organisms, whereas their adequate presence would prevent the entrance of pathogens into the blood stream; that due to their cobalt content the articles would help to mature red blood cells, depress certain intestinal pathogens, activate internal micro-organisms that split carbohydrates and proteins for better food assimilation, perform enzyme and enzyme substrate functions in the form of a metal proteid, and were of fundamental importance; that because of their cobalt sulfate content, the articles would relieve deficiencies when administered orally; that due to their manganese content, the articles would act as a catalyst to bind calcium and phosphorus into bones, help to perform chemical reactions and to reverse them, and activate iron and conduct it to the proper place in the hemoglobin molecule of the red blood cells; that manganese is as important as iron for the generation and regeneration of hemoglobin because it is in all probability the coenzyme of a proteid in hemoglobin synthesis; that manganese is related to the formation of the vitamins A, C, and E; that the articles were a positive cure for diabetes; that supplements of inorganic nutriments have certain advantages when they contain available sulfate ions; that the effect of sulfates in the articles was buffered by the lecithin present; that the articles would balance the contents of essential inorganic bio-elements in modern diets; that the articles were an adequate and effective treatment for Brucella infection (undulant fever), and such symptoms as alternating fevers and chills, headaches, backaches, pains behind the knees, loss of weight, loss of strength, olive-colored skin, intolerance to light, fear of imminent danger, gastric ulcers, arthritis, rheumatism and

influenza, mastitis, caked breast, diabetes, Buerger's disease (thromboangiitis obliterans), arthritic conditions, sciatica, lumbago, bone fractures (nonhealing bones), Paget's disease, sterility before and during treatment with hormones, and all cases of malnutrition, nervousness, stomach trouble, and incurable eczema; that the articles were effective as a nutritional fortification before and after surgical operations and during period of pregnancy and nursing; and that the administration of sulfa drugs, antibiotics, and vitamins would be more effective when preceded and followed by the articles. These statements were contrary to fact.

Soyabean oil. Misbranding, Section 502 (a), certain statements in the leaflet which accompanied the article and which was entitled "Retail Price List" were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for poor skin conditions, underweight, arthritis, and scaly skin. The article was not an adequate and effective treatment for these conditions.

Soya lecithin. Misbranding, Section 502 (a), certain statements in the circular entitled "Oil Free Soyabean Lecithin Edible" and leaflet entitled "Retail Price List," which accompanied the article, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for hardening of the arteries, high and low blood pressure, hypertension, calcination of the spine or other parts of the skeleton, psoriasis, and pulmonary troubles; that it was effective in the prevention of fatty livers; and that it would check tendencies toward arteriosclerosis. These statements were contrary to fact.

The articles were misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: January 14, 1952. Default decree of condemnation and destruction.

3794. Misbranding of In-Flam-Go. U. S. v. 60 Bottles, etc. (F. D. C. No. 33236. Sample No. 31615–L.)

LIBEL FILED: May 6, 1952, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about July 25, 1951, by the In-Flam-Go Products Co., from Detroit, Mich.

PRODUCT: 60 1-pint bottles and 95 ½-pint bottles of *In-Flam-Go*, at St. Louis, Mo., together with a number of leaflets headed "It Will Surprise You" and "A Truly Remarkable Product" and a display easel headed "In-Flam-Go," which accompanied the product. Analysis showed that the product was an oily solution containing a small amount of iodine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label, in the accompanying leaflets, and on the display easel were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for inflammation, goiter, varicose veins, sprains, arthritis, neuritis, styes, burns and scalds, underactive and overactive thyroid glands, neuralgia, backache, sore muscles, bruises, impetigo, varicose ulcers, gangrene, hardening of the arteries, tonsilitis, sore throat, ringworm, eczema, sinus conditions, swelling of the glands, and high blood pressure. The article was not an adequate and effective treatment for such conditions.

DISPOSITION: June 27, 1952. Default decree of condemnation and destruction.

3795. Misbranding of Ebrey Extract. U. S. v. 144 Bottles * * *. (F. D. C. No. 33235. Sample No. 38153–L.)

LIBEL FILED: May 8, 1952, Southern District of New York.

ALLEGED SHIPMENT: On or about July 13, 1951, by the Ebrey Chemical Works, from Humacao, P. R.

PRODUCT: 144 3-ounce bottles of *Ebrey Extract* at New York, N. Y. Some of the bottles were labeled in the Spanish language, and others were labeled in part in the Spanish language and in part in the English language.

LABEL, IN PART: "Anticalculina Ebrey Extracto Ebrey Indicada Como Diuretico Y En Los Catarros Vesicales" or "Ebrey Extract A Soothing Diuretic to Kidneys and Bladder Alcohol 28% Active Ingredients: Fluid Extracts of Uva Ursi, Buchu, Corn-Silk (Zea), Sabal (Serenoa), Cubeb and Juniper, compounded with physiologically inactive Chlorophyll as an excipient. Contents 3 fl. ounces."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements "Anticalculina * * * Indicada Como Dieuretico Y En Los Catarros Vesicales" appearing on some of the bottle labels and the statement "Soothing Diuretic to Kidneys and Bladder" appearing on some of the bottle labels and on all of the carton labels were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for kidney stones, bladder stones, inflammation of the bladder, and irritations of the kidneys and bladder. The article was not an adequate and effective treatment for such conditions.

DISPOSITION: July 3, 1952. Default decree of condemnation and destruction.

3796. Misbranding of Sobar. U. S. v. 67 Bottles, etc. (F. D. C. No. 33318. Sample No. 37646–L.)

LIBEL FILED: July 1, 1952, Southern District of New York.

ALLEGED SHIPMENT: During October 1951, by Horace M. Carter, from Rutland, Vt.

PRODUCT: 67 ½-ounce bottles of *Sobar* at New York, N. Y., in possession of Frailey Industries, Inc., together with a number of streamers reading "Morning after? Get Sobar Ask Prescription Clerk" and "For Relief of Overindulgence in Alcoholic Beverages Morning after? Get Sobar" and a number of leaflets entitled "SOBAR What It Is," which streamers and leaflets were printed locally for the consignee.

LABEL, IN PART: (Bottle) "SOBAR For the relief of the symptoms of ordinary Overindulgence in Alcoholic Beverages Active Ingredients: Chlorophyllins * * * Thiamine Hydrochloride, U. S. P. Sodium Salicylate, U. S. P. Citrated Caffeine, U. S. P. Alcohol 23% * * * Distributed by Frailey Industries, Inc. New York, N. Y. * * * To 'sober up' quickly."

NATURE OF CHARGE: Misbranding, Section 502 (a), the bottle labels contained the designation "Sobar" and statements which represented and suggested that the article was an adequate and effective treatment for acute alcoholism, which statements were false and misleading since the article was not an adequate and effective treatment for acute alcoholism. The article was misbranded in this respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the leaflets and streamers accompanying the article contained statements which represented and suggested

that the article was an adequate and effective treatment for acute alcoholism and was capable of oxidizing the alcohol in the system quickly, which statements were false and misleading since the article was not effective for such purposes. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: August 22, 1952. Default decree of condemnation and destruction.

3797. Misbranding of Shiatsuryoho Instrument (also known as Shiatsuryoki Instrument). U. S. v. 134 Devices * * *. (F. D. C. No. 31978. Sample No. 28399–L.)

LIBEL FILED: November 5, 1951, District of Hawaii.

ALLEGED SHIPMENT: On or about December 26, 1950, by Tatemi Fukunaga Nippon Kosan, Inc., from Tokyo, Japan.

PRODUCT: 134 *Shiatsuryoho Instruments* (also known as Shiatsuryoki Instruments) at Honolulu, T. H., together with a number of booklets entitled "The distinguished features of the newly designed instrument 'Shiatsuryoki' " and a number of leaflets entitled "Shiatsuryoho Instrument."

The device consisted of a group of metal needle points mounted on the end of a core, so encased in a tube with a spring that by hand pressure the needle points can be protruded from the end of the tube against the skin.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above booklets and leaflets accompanying the devices were false and misleading. The statements represented and suggested that the device was an adequate and effective treatment for neuralgia, rheumatism, stiff back, mental disease, giddiness, arteriosclerosis, nervous break-down, hysteria, headache, facial neuralgia, insomnia, eye conjunctivitis leading to blindness, earache, hiccoughing, nasal catarrh, tonsillitis, upper limb ailments, asthma, hemorrhage of lungs, thyroid trouble, morbus basedow, eye disease, liver and gall ailments, intestinal tuberculosis, bronchitis, heart disorders, heart and bronchial ailments, pleurisy, pneumonia, heart paroxysm, jaundice, hyperaemia, acidosis, stomach trouble, chills, skin eruptions, diarrhea, mumps, indigestion, dilatation of stomach, stomach catarrh, stomach ulcers, gastroptosis, intercostal neuralgia, diabetes, pancreas trouble, ailments of intestines, malaria, polio, bladder trouble, uremia, obesity, lumbago, nephritis, nervous disorder of upper colon, ailment of uterus and prostate gland, dislocation of stomach, intestines, colon, and uterus, sterility, constipation, menorrhea, orchitis (inflammation of testicles), ovaritis, leucorrhea, suppression of menses, piles, rupture, backache, hip gout, difficulty in walking, colds, coughing, diseases of genital organs, heart diseases, splenetic ailment, peritonitis, cystitis, gonorrhea, habitual constipation, sinus trouble, bed wetting, tympanitis, toothache, inflammation of lymphatic gland, whooping cough, goiter, low fever, neuritis, atonia, castroptosis, colon catarrh, appendicitis, and beriberi; and that the device was an adequate and effective treatment to vitalize the bodily function, to accelerate regeneration, to stimulate blood circulation, causing the white corpuscles of the blood to destroy bacteria which might be present in the locality of the ailment, and to cause physiological readjustment, resistance, and recovery. The statements were false and misleading since the device was not an adequate and effective treatment for the above conditions.

DISPOSITION: July 31, 1952. Default decree of condemnation and destruction.

3798. Misbranding of MacLevy hand massagers. U. S. v. 10 Devices, etc. (F. D. C. No. 32220. Sample No. 32371–L.)

LIBEL FILED: December 6, 1951, Eastern District of Arkansas.

ALLEGED SHIPMENT: On or about August 21, 1951, by the MacLevy Equipment Corp., from New York, N. Y.

PRODUCT: 10 *MacLevy hand massagers* and 9 leaflets entitled "Reduce At Home" at Pine Bluff, Ark. The device consisted of 4 rubber balls mounted on a metal shaft with a handle at each end.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying leaflets entitled "Reduce At Home" were false and misleading since they represented and suggested that the device would be effective to bring about a reduction in weight, whereas the device would not be effective for that purpose.

DISPOSITION: January 24, 1952. Default decree of condemnation. The court ordered that the 5 devices which actually were seized under the libel and the leaflets be delivered to the Food and Drug Administration for exhibit purposes.

3799. Misbranding of Therm-Massage infrared heat applicator. U. S. v. 2,000 Cartons, etc. (F. D. C. No. 32221. Sample No. 3702–L.)

LIBEL FILED: On or about December 4, 1951, District of Maryland.

ALLEGED SHIPMENT: On or about October 25 and 26, 1951, from Newark, N. J.

PRODUCT: 2,000 *Therm-Massage infrared heat applicators* in individual cartons at Baltimore, Md., together with a number of cards headed "Infra-Red Therm-Massage Heat Applicator." The cards were printed locally.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the above-mentioned cards accompanying the device were false and misleading since the device was not an adequate and effective treatment for the conditions stated and implied and was not capable of fulfilling the promises of benefit made for it: "Infra-Red Therm-Massage Heat Applicator * * * Indicated for * * * aching joints, backache, rheumatism, aching muscles, foot cramps, arthritis, stiff neck, sinus, neuritis * * * sprains * * * leg cramps * * * Is your Family Protected Right Now? * * * Notice how quickly sore muscles begin to relax, aching nerves and joints feel better * * * Pain may come suddenly. Here's quick convenient inexpensive relief * * * Say No, to aches and pains * * * Arthritis Relief * * * have had arthritis for many years and this * * * has * * * given me relief * * * (pictures with legends 'Back Pains! Foot Pains! Sprains, bruises, foot and leg cramps. Head Pains! Soothing Infra-Red Heat and Massage for colds, headache, sinus')." The device was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 8, 1952. National Health Aids of Baltimore, Inc., Baltimore, Md., having appeared as claimant and filed an answer to the libel, and later having withdrawn its answer, judgment of condemnation was entered and the court ordered that the devices be destroyed. On September 10, 1952. an order was entered providing for the delivery of three of the devices and their labeling to the Food and Drug Administration.

3800. Misbranding of Le Joi devices. U. S. v. 822 Devices, etc. (F. D. C. No. 33197. Sample No. 17207–L.)

LIBEL FILED: April 24, 1952, Southern District of California; amended libel filed April 24, 1952.

ALLEGED SHIPMENT: On or about February 21 and March 3, 12, 14, 18, and 24, 1952, from Minneapolis, Minn.

PRODUCT: 822 *Le Joi devices* at Los Angeles, Calif., in possession of Pro-Tex, Inc., together with accompanying leaflets entitled "Instructions Le Joi" and "New Horizons." The latter leaflet had been printed locally for the above corporation. Examination showed that the device consisted of a thin rubber tube with a locking attachment at each end.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying leaflets "New Horizons" were false and misleading. The statements represented and suggested that use of the device was effective in improving the sexual capacities of older men by enlarging and reinforcing the sexual organ. The device was not effective for such purposes, and it would not fulfill the promises of benefit made for it. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: August 13, 1952. Vita Pharmacals, Inc., Los Angeles, Calif., having filed its claim and answer to the libel and subsequently having withdrawn such claim and answer, judgment of condemnation was entered and the court ordered that the 2 devices which actually were seized under the libel be delivered to the Food and Drug Administration.

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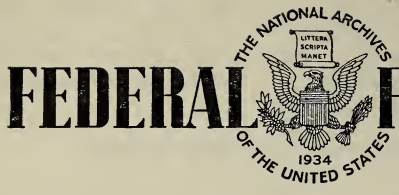
[1] (3785) Prosecution contested. Contains opinions of the court.

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[1] (3785) Prosecution contested. Contains opinions of the court.



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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3801–3820

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *February 10, 1953.*

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DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3801. Adulteration and misbranding of dextro-amphetamine sulfate tablets and amphetamine sulfate tablets. U. S. v. 232,000 Tablets, etc. Tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 31408. Sample Nos. 20953–L, 20987–L, 20988–L.)

LIBEL FILED: On or about August 3, 1951, Northern District of Texas; amended on or about September 21, 1951.

ALLEGED SHIPMENT: On or about January 29, 1951, by the Kumfort Drug Products Co., from Cleveland, Ohio.

PRODUCT: 232,000 *dextro-amphetamine sulfate tablets* and 15,000 *amphetamine sulfate tablets* in labeled and unlabeled bottles at Dallas, Tex., in possession of Ward's Cut Rate Drugs.

Analysis showed that the 232,000-tablet lot contained 5 mg. of a mixture of racemic and dextro-amphetamine sulfate per tablet and that the 15,000-tablet lot contained 6.5 mg. of amphetamine sulfate per tablet.

RESULTS OF INVESTIGATION: The articles were shipped in unlabeled bottles, and portions of both articles were labeled by the consignee.

NATURE OF CHARGE: Adulteration, Section 501 (d), (232,000-tablet lot) a substance, namely, tablets each containing 5 mg. of a mixture of racemic and dextro-amphetamine sulfate, had been substituted for 5 mg. *dextro-amphetamine sulfate tablets*, and (15,000-tablet lot) a substance, namely, 6.5 mg. amphetamine sulfate tablets, had been substituted for 10 mg. *amphetamine sulfate tablets*. Misbranding, Sections 502 (b) (1) and (2), (unlabeled bottles) the articles failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Sections 502 (f) (1) and (2), the labeling of the articles failed to bear adequate directions for use and such adequate warnings against use where their use may be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form, as are necessary for the protection of users. The articles were adulterated and misbranded in these respects when introduced into, while in, and while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (e) (2), (232,000-tablet lot) the label of the article failed to bear the common or usual name of each active ingredient. The article was misbranded in this respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the label designations, namely, (232,000-tablet lot) "Dextro Amphetamine Sulfate 5 Mg." and (15,000-tablet lot) "Racemic Amphetamine Sulfate 10 Mg.," were false and misleading as applied to articles containing, respectively, 5 mg. of a mixture of racemic and dextro-amphetamine sulfate per tablet and 6.5 mg. of amphetamine sulfate per tablet. The articles were misbranded in these respects while held for sale after shipment in interstate commerce.

DISPOSITION: Ward's Cut Rate Drugs having appeared as interveners, the case came on for trial before the court without a jury, on September 24, 1951. At the conclusion of the trial, the court found that the law and the facts were with the Government, and on September 26, 1951, a decree of condemnation and destruction was entered.

3802. Misbranding of thyroid tablets, Neotresamide tablets, amphetamine sulfate tablets, phenobarbital tablets, diethylstilbestrol tablets, and methyltestosterone tablets. U. S. v. Arthur Weiler (Weiler's Drug Store), Lester E. Dorris, and Leonard Kehoe. Pleas of guilty. Defendant Weiler fined $800, plus one-half of the costs, and Defendants Dorris and Kehoe each fined $100, plus one-fourth of the costs. (F. D. C. No. 31307. Sample Nos. 30856–L, 31169–L, 31170–L, 31180–L, 31289–L, 31938–L.)

INFORMATION FILED: February 27, 1952, Eastern District of Illinois, against Arthur Weiler, trading as Weiler's Drug Store, Paris, Ill., and against Lester E. Dorris and Leonard Kehoe, pharmacists.

ALLEGED VIOLATION: On or about May 9 and 23 and June 5, 1951, while a number of *thyroid tablets*, *Neotresamide tablets*, *amphetamine sulfate tablets*, *phenobarbital tablets*, *diethylstilbestrol tablets*, and *methyltestosterone tablets* were being held for sale at Weiler's Drug Store after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded.

Arthur Weiler was charged in each of the six counts of the information, Lester E. Dorris, in five of the counts, and Leonard Kehoe, in one of the counts, with causing the acts of repacking and dispensing of the drugs involved.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use; and, Section 502 (b) (1), the repackaged *phenobarbital tablets* failed to bear a label containing the name and address of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the label of the repackaged *Neotresamide tablets* failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), the labeling of the repackaged *Neotresamide tablets* failed to bear adequate warnings against use.

DISPOSITION: September 18, 1952. Pleas of guilty having been entered, the court fined Defendant Weiler $800, plus one-half of the costs, and Defendants Dorris and Kehoe $100 each, plus one-fourth of the costs.

3803. Misbranding of Belladenal tablets. U. S. v. Wm. W. Myer Drug Stores Co., and Theodore J. Nelligan, Roy Roscoe Brown, and Harry L. Brawley. Pleas of guilty. Fine of $750 against firm, $250 against Defendant Nelligan, $100 against Defendant Brown, and $100 against Defendant Brawley. (F. D. C. No. 31295. Sample Nos. 13378–L, 13379–L.)

INFORMATION FILED: December 26, 1951, District of Colorado, against the Wm. W. Myer Drug Stores Co., a corporation, Denver, Colo., and Theodore J. Nelligan, manager of the corporation's store at 400 17th St., Denver, Colo., and Roy Roscoe Brown and Harry L. Brawley, pharmacists at the above store.

ALLEGED VIOLATION: On or about February 27 and March 1, 1951, while a number of *Belladenal tablets* were being held for sale at the above-mentioned

store after shipment in interstate commerce, the defendants caused a number of tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drug contained phenobarbital, a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the drug failed to bear a label containing the name, and quantity or the proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged drug was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of the active ingredient, phenobarbital, and the name, and quantity or proportion of the ingredient, hyoscyamine; and, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: June 18, 1952. The corporation and Defendants Nelligan and Brown having entered pleas of guilty to count 1 of the information and Defendant Brawley having entered a plea of guilty to count 2 of the information, the court imposed a fine of $750 against the corporation, $250 against Defendant Nelligan, $100 against Defendant Brown, and $100 against Defendant Brawley.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3804. Adulteration and misbranding of allylisopropyl barbiturate sodium capsules and Hemotene tablets. U. S. v. Midwest Chemical Development Corp. Plea of nolo contendere. Fine, $400. (F. D. C. No. 31581. Sample Nos. 10142–L, 16763–L.)

INFORMATION FILED: February 7, 1952, Northern District of Ohio, against the Midwest Chemical Development Corp., from Cleveland, Ohio.

ALLEGED SHIPMENT: On or about March 2, 1951, from the State of Ohio into the States of Michigan and California.

LABEL, IN PART: "Manufactured for: Diacin Chemical Co. * * * Detroit, Michigan * * * Each capsule contains: Allyl Isopropyl Barbiturate Sodium 1½ gr." and "270 Tablets Hemotene With Organic Iron and B–12 Distributed by Halco Corp. Los Angeles, Calif. Six Hemotene Tablets provide: * * * Vitamin C 120 milligrams Vitamin D 2000 U. S. P. Units."

NATURE OF CHARGE: *Allylisopropyl barbiturate sodium capsules.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since it contained less than 1½ grains of allylisopropyl barbiturate sodium per capsule as represented. Misbranding, Section 502 (a), the label declaration "Each capsule contains: Allyl Isopropyl Barbiturate Sodium 1½ gr." was false and misleading.

Hemotene tablets. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since 6 tablets of the article were represented to supply 120 mg. of vitamin C and 2,000 U. S. P. units of vitamin D, whereas 6 tablets would supply lesser

amounts of such vitamins. Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since the statements represented and suggested that 6 tablets of the article would supply 120 mg. of vitamin C and 2,000 U. S. P. units of vitamin D, and would supply four times the minimum daily requirements for vitamin C and five times the minimum daily requirements for vitamin D, whereas the article would supply smaller amounts of vitamin C and vitamin D than was represented and smaller proportions of the minimum daily requirements for vitamin C and vitamin D than was represented.

The information alleged also that another article, known as vitamin A and D tablets, was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: June 27, 1952. A plea of nolo contendere having been entered, the court imposed a fine of $400.

3805. Adulteration of sulfadiazine tablets. U. S. v. 19 Bottles * * *. (F. D. C. No. 33276. Sample No. 6556–L.)

LIBEL FILED: May 26, 1952, District of Massachusetts.

ALLEGED SHIPMENT: On or about May 5, 1952, by the Robin Pharmacal Corp., from Brooklyn, N. Y.

PRODUCT: 19 1,000-tablet bottles of *sulfadiazine tablets* at Boston, Mass.

LABEL, IN PART: (Bottle) "1000 Sulfadiazine * * * (2-Sulfanilamidopyrimidine) Compressed Tablets (Scored) 0.5 Gm. (7.7 Grains)."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sulfadiazine Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since the standard provides that sulfadiazine tablets contain not less than 95 percent of the labeled amount of sulfadiazine, whereas the article contained less than that amount, namely, not more than 77 percent of the labeled amount of sulfadiazine.

DISPOSITION: August 18, 1952. The Robin Pharmacal Corp., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the drug be released under bond for reprocessing to bring it into compliance with the law, under the supervision of the Federal Security Agency.

3806. Adulteration of sodium salicylate and iodide with colchicine. U. S. v. 10 Cartons, etc. (F. D. C. No. 33338. Sample Nos. 7723–L, 7724–L.)

LIBEL FILED: July 9, 1952, Western District of New York.

ALLEGED SHIPMENT: On or about May 16, 1952, by the Addison Laboratories, from Philadelphia, Pa.

PRODUCT: 20 cartons, each containing 50 ampuls, of *sodium salicylate and iodide with colchicine* at Buffalo, N. Y. Examination showed that some of the ampuls contained less than the declared amounts of the sodium salicylate and sodium iodide ingredients, and that some of the ampuls (15.5 grain strength) contained the drug aminophylline instead of the declared ingredients.

LABEL, IN PART: (Ampul) "Size: 20 cc. * * * Sodium Salicylate and Iodide with Colchicine Each 20 cc. contain a sterile solution of: Sodium Iodide . . . . . 15.5 gr. Sodium Salicylate . . . . . 15.5 gr. Colchicine . . . . . 0.65 mg." and "Size: 20 cc. * * * Sodium Salicylate and Iodide with

Colchicine Each 20 cc. contain a sterile solution of Sodium Salicylate . . . . . 31 gr. Sodium Iodide . . . . . 31 gr. Colchicine . . . . . 0.65 gr."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sodium Salicylate and Iodide with Colchicine," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium.

Further adulteration, Section 501 (d) (2), in the case of some of the ampuls (15.5 grain strength), a substance, aminophylline, had been substituted in whole or in part for the article.

DISPOSITION: August 12, 1952. Default decree of condemnation and destruction.

3807. Adulteration and misbranding of vitamin C tonic. U. S. v. 139 Bottles * * *. (F. D. C. No. 32555. Sample No. 23469–L.)

LIBEL FILED: February 29, 1952, Eastern District of New York.

ALLEGED SHIPMENT: On or about June 11, 1951, by Kegan Laboratory, Inc., from Englewood, N. J.

PRODUCT: 139 8-ounce bottles of *vitamin C tonic* at Brooklyn, N. Y. Analysis showed that the product contained approximately 21 percent of the declared amount of vitamin C.

LABEL, IN PART: (Bottle) "C-Tone Natural Vitamin C Tonic * * * Each day's supply of 4 tablespoons furnishes: Natural Vitamin C 250 Mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 250 mg. of vitamin C. Misbranding, Section 502 (a), the label statement "4 tablespoons furnishes: Natural Vitamin C 250 Mg." was false and misleading as applied to the article, which furnished less than the stated amount of vitamin C. The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (a), the label statements "C-Tone rapidly builds up bodily stores of this essential vitamin, deficiency of which may contribute to many chronic ailments * * * to help reduce irritations in the stomach and intestinal tract" were false and misleading since the article was not effective to prevent and correct many chronic ailments and to reduce irritation in the stomach and intestinal tract. The article was misbranded in this respect when introduced into and while in interstate commerce.

DISPOSITION: October 27, 1952. Default decree of condemnation and destruction.

3808. Adulteration and misbranding of powdered hand soap. U. S. v. 7 Cartons, etc. (F. D. C. No. 29374. Sample No. 57038–K.)

LIBEL FILED: June 28, 1950, Eastern District of New York.

ALLEGED SHIPMENT: On or about March 30, 1950, by the Sanitary Soap Co., from Paterson, N. J.

PRODUCT: 7 cartons, each containing 6 5-pound packages, of *powdered hand soap* at Brooklyn, N. Y., together with a number of leaflets entitled "The Best Hand Soap In The World." Bacteriological tests of the product showed that it was not antiseptic.

LABEL, IN PART: "Antiseptic Lanelle Powdered Hand Soap."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess since it was not antiseptic.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading: (Package label) "Antiseptic Lanelle is highly germicidal. It kills germs on contact. It is especially deadly against the most common disease, infection spreading germs. Lanelle will serve as real protection against dermatitis and occupational skin infections. * * * use antiseptic Lanelle daily for protection against disease and infection * * * Antiseptic Lanelle's germicidal lather. * * * protection against infection. Plus another wonderful ingredient which greatly activates the lanolin, * * * All Antiseptic Lanelle's germicidal, * * * values have been proven by unbiased laboratory tests made with America's largest testing laboratories. * * * Germ Killing * * *" and (leaflet entitled "The Best Hand Soap In the World") "* * * Germicidal—positive medical protection against skin infection * * *." These statements represented and suggested that the article was antiseptic, whereas it was not antiseptic.

DISPOSITION: November 10, 1952. The Sanitary Soap Co., claimant, filed an answer denying the adulteration and misbranding of the product as alleged and served written interrogatories upon the Government which were answered. Thereafter, the claimant consented to the entry of a decree, as prayed for in the libel. Accordingly, judgment of condemnation was entered, and the court ordered that the product be destroyed.

3809. Adulteration and misbranding of clinical thermometers. U. S. v. 105 Clinical Thermometers. (F. D. C. No. 33314. Sample No. 3731-L.)

LIBEL FILED: June 27, 1952, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about April 18, 1952, by the Dependable Thermometer Co., from Bronx, N. Y.

PRODUCT: 105 *clinical thermometers* at Norfolk, Va. Examination of 15 thermometers taken from the shipment showed that one was a hard shaker; that one failed to meet the test for retreating index; and that eight lost the pigment, in a water bath, from 1 to 19 of the engraved graduation marks.

LABEL, IN PART: (Carton) "One Certified Fever Thermometer * * * Type Rectal."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess, namely, "in compliance with the specifications of the National Bureau of Standards."

Misbranding, Section 502 (a), the label statement "GUARANTEE—This thermometer * * * Manufactured and tested in compliance with the specifications of the National Bureau of Standards * * *" was false and misleading since the article did not comply with such specifications.

DISPOSITION: October 10, 1952. Default decree of condemnation and destruction

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE

3810. Misbranding of S-L-Gran (soya lecithin) U. S. v. 53 Bottles * * *. (F. D. C. No. 33260. Sample No. 1979-L.)

LIBEL FILED: May 21, 1952, Southern District of Florida.

ALLEGED SHIPMENT: On or about December 28, 1951, and February 15, 1952, from Chicago, Ill.

PRODUCT: 53 7-ounce bottles of *S-L-Gran (soya lecithin)* in possession of the S-L-Gran Agency of Croft Hardware at Miami, Fla., together with a number of circulars entitled "Edible Soya Lecithin A Dietary Supplement."

RESULTS OF INVESTIGATION: The product was shipped in a drum, and upon receipt by the consignee, the product was repackaged into bottles and relabeled.

LABEL, IN PART: (Bottle) "S-L-Gran (Soya Lecithin) A natural food product that helps relieve poor circulation; reduces excess cholesterol, a fatty substance, in the blood."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in the above-mentioned circular accompanying the article were false and misleading. The statements represented and suggested that the article was effective to help relieve poor circulation, to remove excess fat from the liver, to promote liver functioning, to check tendency towards hardening of the arteries, to reduce blood pressure, to help solve the problem of psoriasis and arthritis, and to eradicate incapacitating and continuously painful arthritis calcination of the spine, arteriosclerosis, swollen finger joints, serious muscle spasms, failing blood supply, constriction of the arteries, stroke, impaired mobility, blurred vision, dizziness, foggy headaches, and ringing in the ears. The article was not effective for such purposes. The article was misbranded in the above respect while held for sale after shipment in interstate commerce.

DISPOSITION: June 11, 1952. Default decree of forfeiture and destruction.

3811. Misbranding of Vita-Long tonic. U. S. v. 1,338 Bottles * * *. (F. D. C. No. 33408. Sample No. 22502–L.)

LIBEL FILED: June 19, 1952, Southern District of Texas.

ALLEGED SHIPMENT: On or about October 22, 1951, by Dr. George S. Long Corp., from Pineville, La.

PRODUCT: 1,338 8-ounce bottles of *Vita-Long tonic* at Houston, Tex.

LABEL, IN PART: "Vita-Long To Be Used As A Vitamin Tonic For Young And Old."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in an accompanying leaflet entitled "Read what others say about Vita-Long," were false and misleading. The statements represented and suggested that the article would be effective in the treatment of fatigue, nervousness, loss of appetite, irritability, depression, poor complexion, arthritis, gall bladder trouble, stomach trouble, indigestion, rheumatism, and muscular aches and pains, whereas the article would not be effective for such purposes.

DISPOSITION: July 23, 1952. Default decree of condemnation and destruction.

3812. Misbranding of concentrated extract of alfalfa. U. S. v. 6 Bottles, etc. (F. D. C. No. 33288. Sample No. 27976–L.)

LIBEL FILED: June 17, 1952, Northern District of California.

ALLEGED SHIPMENT: On or about November 1, 1951, and May 2, 1952, by the Lucerne Laboratories of Utah, from American Fork, Utah.

PRODUCT: 6 1-quart bottles, 10 1-pint bottles, and 28 8-ounce bottles of *concentrated extract of alfalfa* at San Francisco, Calif. Examination showed that the product was a mixture of reducing sugars, citric acid, and a small quantity of plant extractions from roasted alfalfa.

LABEL, IN PART: (Bottle) "Lucerne Concentrated extract of Alfalfa with active principle of vitamin B_{12} added * * * It is a Beverage Food Supplement * * * It furnishes minerals contained in Alfalfa * * * May Help to relieve fatigue."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the article and in an accompanying circular entitled "Lucerne (Lucerne is the Old World name for Alfalfa)" were false and misleading since the article supplied no demonstrable amount of B_{12} and was not effective for the purposes, diseases, and conditions stated and implied: (Bottle label) "* * * Concentrated extract of Alfalfa with active principle of vitamin B_{12} added * * * May Help to relieve fatigue" and (circular) "* * * concentrated extract of alfalfa with the active principle of vitamin B_{12} * * * may act as an antifatigue, and as an analgesic. It may calm the nervous system and thus enable All-Wise Nature to aid in relief from such conditions as Rheumatism, Arthritis, Neurasthenia, Exhaustion and General Debility."

The article was alleged to be misbranded also under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: September 10, 1952. Default decree of condemnation and destruction.

3813. Misbranding of Growzon. U. S. v. Demetrios E. Condoyiannis (Growzon Laboratory). Plea of guilty. Fine of $200 or imprisonment for 180 days. (F. D. C. No. 32715. Sample No. 24987–L.)

INFORMATION FILED: August 29, 1952, District of Columbia, against Demetrios E. Condoyiannis, trading as Growzon Laboratory, Washington, D. C.

ALLEGED SHIPMENT: On or about June 6, 1951, from the District of Columbia into the State of Pennsylvania.

LABEL, IN PART: "Growzon For Hair and Scalp * * * Active Ingredients: Viosterol, Vitamin D, Lemon Oil, White Mineral Oil, Glycerine, Magnesii Sulfas 8 Fl. Oz."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in a leaflet headed "Growzon's Message to You," which accompanied the article, were false and misleading. The statements represented and suggested that the article would be efficacious to prevent baldness and cause the growth of new hair and to combat scalp infections and disorders of the scalp, whereas the article would not be efficacious for such purposes.

DISPOSITION: September 30, 1952. A plea of guilty having been entered, the court sentenced the defendant to pay a fine of $200 or serve 180 days in jail.

3814. Misbranding of Darrell's RD–5 Formula. U. S. v. 12 Bottles, etc. (F. D. C. No. 33351. Sample No. 14027–L.)

LIBEL FILED: July 29, 1952, District of Colorado.

ALLEGED SHIPMENT: On or about January 30 and June 12, 1952, by Darrell's RD–5 Products Co., from Salt Lake City, Utah.

PRODUCT: 12 16-ounce bottles, 29 8-ounce bottles, and 74 4-ounce bottles of *Darrell's RD–5 Formula* at Denver, Colo., together with a number of accom-

panying brochures headed "Darrell Foremost authority on hair and scalp care * * * asks * * * Are You One Of These?"

LABEL, IN PART: (Bottle) "Darrell's RD–5 Formula The Scientific Formula for Hair & Scalp Active Ingredients Liquid Carbonic Detergens (Coal Tar Derivative), Resorcinal, Alcohol 40%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying brochures were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for scalp conditions associated with scaling, itching, and baldness, whereas the article was not an adequate and effective treatment for such conditions.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to state the kind of alcohol present in the article and failed to bear the common or usual name of the ingredient listed as "Liquid Carbonic Detergens."

DISPOSITION: September 10, 1952. Default decree of condemnation and destruction.

3815. Misbranding of Marvel's hair and scalp conditioner. U. S. v. 112 Cartons * * *. (F. D. C. No. 31932. Sample No. 16045–L.)

LIBEL FILED: October 23, 1951, Western District of Oklahoma.

ALLEGED SHIPMENT: On or about July 17 and September 20, 1951, by Marvel Industries, Inc., from San Antonio, Tex.

PRODUCT: 112 cartons, each containing 1 bottle, of *Marvel's hair and scalp conditioner* at Oklahoma City, Okla. Analysis showed that the product contained a lead salt, sulfur, alcohol, and a small proportion of quinine.

LABEL, IN PART: (Bottle) "Marvel's Nature Hair and Scalp Conditioner."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, on the bottle and carton labels, in a folder entitled "Marvel's Nature's Hair and Scalp Conditioner is keeping hair healthy for thousands," and in a leaflet entitled "Facts you should know about Marvel," which were shipped with the article, were false and misleading. The statements represented and suggested that the article was effective to stop the falling of hair, to make new hair grow, to remedy premature baldness, to restore hair to its natural color, to cure dandruff, and to keep hair and scalp healthy and protect one from contagious hair and scalp diseases. The article was not effective for such purposes.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

DISPOSITION: September 11, 1952. Marvel Industries, Inc., claimant, having filed a motion for dismissal of the libel and later having withdrawn its motion and consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Food and Drug Administration.

3816. Misbranding of Glycolator devices. U. S. v. 12 Cases, etc. (F. D. C. No. 33321. Sample No. 38743–L.)

LIBEL FILED: June 27, 1952, District of Columbia.

ALLEGED SHIPMENT: On or about May 20, 1952, and subsequent dates, by the Pittsburgh Chemical Laboratory, from Mars, Pa.

PRODUCT: 12 cases, each containing 6 pints, of a liquid known as glycosol, 77 plastic contrivances providing a container for the glycosol, a movable wick, and a heating element known as the "Rex Glycolator," and 24 metal and plastic contrivances consisting of two telescoping parts providing a container for the glycosol, a wick, a variable heating element, and a passageway for air intended to communicate with the air intake opening of a furnace, in possession of John G. Webster & Sons, Inc., at Washington, D. C., together with a number of leaflets entitled "Now We Can Prevent Colds" and a copy of a local newspaper advertisement headed "Developed by John G. Webster Engineers! Amazing New Air Conditioning Method Fights Colds, Viruses, Disease and Death."

The liquid and the metal and plastic contrivances were alleged to constitute a device within the meaning of Section 201 (h).

LABEL, IN PART: (Case) "Glycosol Active ingredient triethylene glycol 90% * * * Iron City Chemical Co. Valencia, Penna."; (plastic contrivances) "The Rex Glycolator * * * Use Glycosol Only * * * Mfd. By Iron City Chemical Co. Evans City, Pa."; (metal and plastic contrivances) "Glycolator * * * Use Glycosol Only * * * Mfg. by Glycolator Div. Iron City Chemical Co. Valencia, Pa."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets accompanying the device were false and misleading. The statements represented and suggested that the device was effective to prevent colds, mumps, German measles, throat and ear infections, infections, and spread of disease, and to protect against colds those persons who spend 8 hours a day in "glycol-vaporized rooms" and are then exposed to colds in buses, subways, theaters, and restaurants. The device was not effective for such purposes, and it was not capable of fulfilling the promises of benefit made for it. The device was misbranded in the above respects when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), certain statements in the labeling of the device, namely, in the above-mentioned newspaper advertisement, were false and misleading. The statements represented and suggested that the device would prevent colds, virus diseases, asthma, respiratory diseases, polio, throat infections, and death due to air-borne bacteria and germs of all kinds. The device would not fulfill the promises of benefit stated and implied. The device was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: August 21, 1952. Default decree of condemnation. The court ordered that a portion of the products be delivered to the Food and Drug Administration and that the remainder be destroyed.

DRUGS FOR VETERINARY USE

3817. Misbranding of Ironated Hog Liquid and Black Hawk's Special Dairy Products. U. S. v. 10 Jugs, etc. (F. D. C. No. 33239. Sample Nos. 48554–L, 48555–L.)

LIBEL FILED: May 9, 1952, District of Nebraska.

ALLEGED SHIPMENT: During May 1951, and on or about February 8, 1952, by the Blackhawk Chemical Co., from Cedar Falls, Iowa.

PRODUCT: 10 1-gallon jugs of *Ironated Hog Liquid* and 15 100-pound bags of *Black Hawk's Special Dairy Products* at Breslau, Nebr., together with a number of order blanks and a number of circulars entitled "Maximum Gain."

Analysis of the *Ironated Hog Liquid* showed the presence of copper and magnesium sulfates, ammonia, and aromatics, but not of potassium permanganate, and of only a negligible trace of iron. Analysis of the *Black Hawk's Special Dairy Products* showed that it contained phosphorus compounds representing not more than 1.5 percent of phosphorus.

NATURE OF CHARGE: *Ironated Hog Liquid.* Misbranding, Section 502 (a), the following statements on the label of the article and on the order blanks accompanying the article were false and misleading: (Jug label) "Ironated Hog Liquid. To aid the control of Ordinary Hog Scours. Ingredients: * * * Potassium Permanganate * * * No other feed necessary during the treatment * * * Feed hog liquid twice weekly when sows are in run down condition. Ironated Hog Liquid should be fed in slop once per week as a tonic for slow growing, unthrifty pigs." and (order blanks) "Hog Liquid (Necro Remedy)." The article would not furnish any significant amount of iron; it contained no potassium permanganate; it was not effective to control any of the ordinary types of scours in hogs; it was not effective for a run-down condition in sows or for slow growing unthrifty pigs; and it was not an effective remedy for "necro."

Black Hawk's Special Dairy Products. Misbranding, Section 502 (a), the following statements on the label of the article and in the accompanying circular entitled "Maximum Gain" were false and misleading: "Shy breeding has been a serious trouble as well as anemia * * * minerals with vitamin D and extra iron and bone building elements will be beneficial far beyond the cost of minerals fed. * * * All Black Hawk Mineral Feeds are fortified with Iron, more Iodine and an increased amount of Vitamins as an aid to overcome and guard against anemia, lump jaw * * *" and "Phosphorus (P) not less than 3.40%." The article was not effective in the treatment, or a preventive, for shy breeding, anemia, and lump jaw, and it contained less than 3.40 percent of phosphorus.

DISPOSITION: June 12, 1952. Default decree of condemnation. The court ordered that the products be disposed of by sale or gift, if possible, or be destroyed. The *Ironated Hog Liquid* was destroyed, and the *Black Hawk's Special Dairy Products* was disposed of for use as stock feed.

3818. Misbranding of Blake's Mineral Compound. U. S. v. 17 Packages * * * (and 2 other seizure actions). (F. D. C. Nos. 33248 to 33250, incl. Sample Nos. 14255–L to 14257–L, incl.)

LIBELS FILED: May 16, 1952, District of New Mexico.

ALLEGED SHIPMENT: On or about January 16, February 25, and April 4, 1952, by the Dencolo Corp., from Denver, Colo.

PRODUCT: 32 packages of *Blake's Mineral Compound* at Springer, Santa Rosa, and House, N. Mex.

LABEL, IN PART: (Package) "Blake's Mineral Compound * * * Ingredients: (active) Ammonium Chloride; Potassium Chlorate; Sodium Sulphate; Calcium Carbonate; Tobacco Powder * * * Hy-Life Mineral Co., 2145 Blake St. Denver, Colo."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. The statements represented and suggested that the article was effective in the prevention and treatment of bloat in sheep and cattle, whereas the article was not effective for such purposes.

Further misbranding, Section 502 (a), the name "Blake's Mineral Compound" and the representations on the label that the declared ingredients were active, coupled with the directions for use, were false and misleading. The name and the representations suggested that the article furnished essential minerals required by sheep and cattle. However, ammonium chloride and sodium sulfate, two of the declared active ingredients, are not required by sheep and cattle; tobacco powder is not a mineral; and, when used as directed, the article would furnish inconsequential nutritional amounts of potassium chlorate and calcium carbonate.

DISPOSITION: July 21, 1952. Default decrees of condemnation and destruction.

3819. Misbranding of Nico tablets. U. S. v. 231 Packages, etc. (F. D. C. No. 33199. Sample No. 33674–L.)

LIBEL FILED: May 15, 1952, Northern District of Illinois.

ALLEGED SHIPMENT: On or about November 24, 1951, from Kansas City, Mo., to Fidelity Laboratories, Inc., Chicago, Ill.

PRODUCT: *Nico tablets.* 231 100-tablet packages, 7 50-tablet packages, 1 100-tablet bottle, and 49 50-tablet bottles at Chicago, Ill.

RESULTS OF INVESTIGATION: The tablets were shipped in bulk, and upon receipt by the consignee, were repackaged into the above-mentioned packages and bottles.

LABEL, IN PART: (Package and bottle) "Nico Tablets (Sheep) For Treatment of Sheep and Goats against large round worms. Contains: Copper Sulfate . . . 6.0 grs. Nicotine Sulfate . . . 1.0 gr. Kaolin.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "For Treatment of Sheep and Goats against large round worms" was false and misleading since the article was not effective in the treatment of large round worms in sheep and goats. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 24, 1952. Default decree of condemnation and destruction.

DRUG ACTIONABLE BECAUSE OF FAILURE TO BEAR A LABEL CONTAINING AN ACCURATE STATEMENT OF THE QUANTITY OF THE CONTENTS

3820. Misbranding of elixir terpin hydrate and codeine. U. S. v. Purepac Corp. Plea of nolo contendere. Fine, $250. (F. D. C. No. 19552. Sample No. 7605–H.)

INFORMATION FILED: July 17, 1946, Southern District of New York, against the Purepac Corp., New York, N. Y.

ALLEGED SHIPMENT: On or about July 11, 1945, from the State of New York into the State of New Jersey.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the labels of the article failed to bear an accurate statement of the quantity of the contents. The labels on the bottles containing the article bore the statement "Two Fluid Ounces," whereas the bottles contained less than 2 fluid ounces.

DISPOSITION: July 18, 1952. A plea of nolo contendere having been entered, the court imposed a fine of $250.

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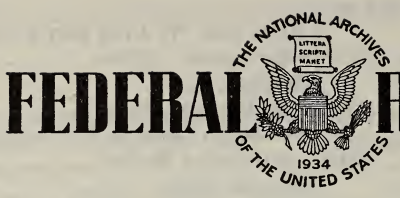
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[1] (3801) Seizure contested.



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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3821–3840

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*
WASHINGTON, D. C., *March 16, 1953.*

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242335—53——1

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

3821. Misbranding of male hormone tablets. U. S. v. 719 Boxes, etc. (F. D. C. No. 33331. Sample Nos. 34692–L, 34693–L.)

LIBEL FILED: July 19, 1952, Western District of Arkansas.

ALLEGED SHIPMENT: On or about May 29, 1952, by Captivante Laboratories, from New York, N. Y.

PRODUCT: 1,377 60-tablet boxes of *male hormone tablets* at Hot Springs, Ark.

LABEL, IN PART: (Box) "Yale Testrex Male Sex Hormones 60 Tablets * * * Ingredients per tablet 2.5 mg. Methyl Testosterone with Ethinyl Estradiol .0025 mg." and "Yale Testrex Male Sex Hormones 60 Tablets—Super-Strength (Double Potency) * * * Ingredients per tablet 5 mg. Methyl Testosterone with Ethinyl Estradiol .0050 mg."

NATURE OF CHARGE: Misbranding, Section 503 (b) (4), the tablets were intended for use by man and were subject to Section 503 (b) (1) (B), and the labels of the tablets failed to bear the statement "Caution: Federal Law prohibits dispensing without prescription."

DISPOSITION: September 23, 1952. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3822. Misbranding of dextro-amphetamine sulfate tablets, phenobarbital tablets, methyltestosterone tablets, and methamphetamine hydrochloride tablets. U. S. v. Glenn M. Stinson (Stinson Drug Store), and Floyd L. Yarbro. Pleas of nolo contendere. Glenn M. Stinson fined $205 and Floyd L. Yarbro fined $60. (F. D. C. No. 32727. Sample Nos. 15509–L to 15511–L, incl., 15513–L, 15514–L, 15520–L, 15523–L.)

INFORMATION FILED: September 18, 1952, Western District of Oklahoma, against Glenn M. Stinson, trading as the Stinson Drug Store, Lawton, Okla., and Floyd L. Yarbro, pharmacist.

INTERSTATE SHIPMENT: Prior to the dates of the sales reported below, various quantities of *dextro-amphetamine sulfate tablets*, *phenobarbital tablets*, *methyltestosterone tablets*, and *methamphetamine hydrochloride tablets* were shipped in interstate commerce into the State of Oklahoma.

ALLEGED VIOLATION: On or about October 11, 13, 15, and 22, 1951, while the drugs were being held for sale at the Stinson Drug Store after shipment in interstate commerce, various quantities of the drugs were repacked and sold without physicians' prescriptions, which acts resulted in the repackaged drugs being misbranded.

Glenn M. Stinson was charged in each of the 7 counts of the information and Floyd L. Yarbro in 4 counts with causing the acts of repacking and sale of the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the *dextro-amphetamine sulfate tablets* were fabricated from two or more ingredients, and the label failed to bear the common or usual name of each active ingredient of the drug; and Section 502 (f) (2), the *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use of the drug in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: October 1, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $205 against Glenn M. Stinson and $60 against Floyd L. Yarbro.

3823. Misbranding of thyroid tablets, dextro-amphetamine sulfate tablets, methyltestosterone tablets, phenobarbital and mannitol hexanitrate tablets, and elixir phenobarbital and thiamine. U. S. v. James H. Ford (Ford's Drug Store), and Bruce R. Lucas. Pleas of nolo contendere. James H. Ford fined $220 and Bruce R. Lucas fined $90. (F. D. C. No. No. 32731. Sample Nos. 15534-L to 15536-L, incl., 15540-L, 15542-L, 15543-L, 15545-L, 15547-L.)

INFORMATION FILED: October 1, 1952, Western District of Oklahoma, against James H. Ford, trading as Ford's Drug Store, Lawton, Okla., and Bruce R. Lucas, a pharmacist.

INTERSTATE SHIPMENT: Prior to the dates of the sales reported below, various quantities of *thyroid tablets*, *dextro-amphetamine sulfate tablets*, *methyltestosterone tablets*, *phenobarbital and mannitol hexanitrate tablets*, and *elixir phenobarbital and thiamine* were shipped in interstate commerce into the State of Oklahoma.

ALLEGED VIOLATION: On or about October 11, 13, 15, and 22, 1951, while the drugs were being held for sale at the Ford's Drug Store after shipment in interstate commerce, various quantities of the drugs were repacked and sold without physicians' prescriptions, which acts resulted in the repackaged drugs being misbranded.

James H. Ford was charged in each of the 8 counts of the information and Bruce R. Lucas in 6 counts with causing the acts of repacking and sale of the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (b) (1), with the exception of the *elixir phenobarbital and thiamine* and one sale of *methyltestosterone tablets*, the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (f) (1), the labeling of the drugs failed to bear adequate directions for use; and, Section 502 (e) (2), the *dextro-amphetamine sulfate tablets* were fabricated from two or more ingredients, and the label failed to bear the common or usual name of each active ingredient of the drug.

Further misbranding, Section 502 (d), the *phenobarbital and mannitol hexanitrate tablets* and the *elixir phenobarbital and thiamine* contained a chemical

derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the labeling of the repackaged drugs failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: October 1, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $220 against James H. Ford and $90 against Bruce R. Lucas.

3824. Misbranding of methyltestosterone tablets, phenobarbital tablets, dextro-amphetamine sulfate tablets, and elixir phenobarbital and thiamine. U. S. v. Public Drug Store. Plea of nolo contendere. Fine, $280. (F. D. C. No. 32728. Sample Nos. 15451–L, 15452–L, 15456–L, 15460–L to 15462–L, incl., 15466–L, 15467–L.)

INFORMATION FILED: September 18, 1952, Western District of Oklahoma, against the Public Drug Store, a partnership, Lawton, Okla.

INTERSTATE SHIPMENT: Prior to the dates of the sales reported below, various quantities of *methyltestosterone tablets*, *phenobarbital tablets*, *dextro-amphetamine sulfate tablets* and *elixir phenobarbital and thiamine* were shipped in interstate commerce into the State of Oklahoma.

ALLEGED VIOLATION: On or about September 28 and October 9, 11, 13, 15, and 22, 1951, while the drugs were being held for sale at the Public Drug Store after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without physicians' prescriptions, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (b) (1), with the exception of the *elixir phenobarbital and thiamine*, the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (f) (1), the drugs failed to bear labeling containing adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *phenobarbital tablets* and the *elixir phenobarbital and thiamine* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of such repackaged drugs failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *methyltestosterone tablets* and *dextro-amphetamine sulfate tablets* were fabricated from two or more ingredients, and they failed to bear labels containing the common or usual name of each active ingredient.

DISPOSITION: October 1, 1952. A plea of nolo contendere having been entered on behalf of the partnership, the court imposed a fine of $280.

3825. Misbranding of methyltestosterone tablets and Sulfonamides Triplex tablets. U. S. v. Lynne E. Steele (Steele Drug Store). Plea of guilty. Fine, $200. (F. D. C. No. 32706. Sample Nos. 13776–L, 13777–L, 13780–L, 13781–L.)

INFORMATION FILED: April 1, 1952, District of Utah, against Lynne E. Steele, trading as the Steele Drug Store, Salt Lake City, Utah.

ALLEGED VIOLATION: On or about September 15, 18, 24, and 25, 1951, while quantities of *methyltestosterone tablets* and *Sulfonamides Triplex tablets* were being held for sale at the Steele Drug Store after shipment in interstate commerce, the defendant caused a number of tablets of such drugs to be repacked and dispensed without physicians' prescriptions, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the repackaged drugs were not designated solely by names recognized in an official compendium and were fabricated from two or more ingredients, and they failed to bear labels containing the common or usual name of each active ingredient; Section 502 (f) (1), the repackaged drugs failed to bear labeling containing adequate directions for use; and, Section 502 (f) (2), the repackaged *Sulfonamides Triplex tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 2, 1952. A plea of guilty having been entered, the court imposed a fine of $200.

3826. Misbranding of sulfadiazine tablets, dextro-amphetamine sulfate tablets, and Seconal Sodium capsules. U. S. v. Toland Dwight Mitchell. Plea of nolo contendere. Fine, $300. (F. D. C. No. 30030. Sample Nos. 70852–K to 70854–K, incl., 70856–K, 70857–K, 70860–K, 70861–K, 70863–K, 70864–K, 70866–K, 70867–K, 70869–K, 70872–K.)

INFORMATION FILED: February 15, 1951, Western District of Oklahoma, against Toland Dwight Mitchell.

ALLEGED VIOLATION: On or about April 23, 24, 25, 26, 28, and 30, 1950, while quantities of *sulfadiazine tablets*, *dextro-amphetamine sulfate tablets*, and *Seconal Sodium capsules* were being held for sale after shipment in interstate commerce, at the stores of Stanro Stores, Inc., operated under the names of Reno Drug Co. and Standard Drug Co., at Oklahoma City, Okla., Toland Dwight Mitchell, president of Stanro Stores, Inc., caused quantities of such drugs to be repacked and disposed of without physicians' prescriptions, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged *sulfadiazine tablets* and *dextro-amphetamine sulfate tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the drug failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), a portion of the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (f) (1), the labeling of all of the repackaged drugs

failed to bear adequate directions for use; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* and *dextro-amphetamine sulfate tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: On March 23, 1951, a motion to quash the information was filed on behalf of the defendant on the grounds that the information was duplicitous, and, in addition, a motion was filed by the defendant for a bill of particulars. On September 27, 1951, the court overruled the motions of the defendant. On January 23, 1952, the defendant entered a plea of nolo contendere, and the court imposed a fine of $300.

3827. Misbranding of Seconal Sodium capsules. U. S. v. Earl O. Meyer Drugs and Earl O. Meyer. Pleas of guilty. Fine of $1,000 against each defendant; individual defendant also placed on probation for 4 years. (F. D. C. No. 32711. Sample No. 12943–L.)

INFORMATION FILED: April 17, 1952, District of Colorado, against the Earl O. Meyer Drugs, a partnership, Denver, Colo., and Earl O. Meyer, a partner in the partnership.

ALLEGED VIOLATION: On or about August 3, 1951, while a number of *Seconal Sodium capsules* were being held for sale at the Earl O. Meyer Drugs after shipment in interstate commerce, the defendants caused a quantity of the capsules to be repacked and dispensed without a physician's prescription, which acts resulted in the capsules being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged capsules failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged capsules failed to bear labeling containing adequate directions for use.

DISPOSITION: October 8, 1952. Pleas of guilty having been entered, the court imposed a fine of $1,000 against each of the defendants, and, in addition, placed the individual defendant on probation for a period of 4 years.

3828. Misbranding of Seconal Sodium capsules. U. S. v. Azriel Stein. Plea of guilty. Fine of $1,000 and probation for 5 years. (F. D. C. No. 31293. Sample No. 13165–L.)

INFORMATION FILED: December 5, 1951, District of Colorado, against Azriel Stein, Denver, Colo.

INTERSTATE SHIPMENT: Prior to April 16, 1951, from the State of Indiana into the State of Colorado, of a quantity of *Seconal Sodium capsules.*

ALLEGED VIOLATION: On or about April 16, 1951, while the capsules were being held for sale at the Pencol Drug Store, Denver, Colo., after shipment in interstate commerce, the defendant, a pharmacist and manager of the drug store, caused a number of the capsules to be repacked and sold without a physician's prescription, which acts resulted in the repackaged capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the article contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: October 8, 1952. A plea of guilty having been entered, the court imposed a fine of $1,000 against the defendant and placed him on probation for a period of 5 years.

3829. Misbranding of Beatsol Rectifiers, Beatsol Drawing Salve, and Beatsol Earache Liquid. U. S. v. Carl J. Greenblatt (G & W Laboratories). Plea of nolo contendere to counts 1, 2, and 3, and plea of guilty to counts 4, 5, and 6. Fine, $900. (F. D. C. No. 30618. Sample Nos. 73363-K, 73364-K, 73367-K, 73379-K, 73382-K, 73638-K.)

INDICTMENT RETURNED: April 22, 1952, District of New Jersey, against Carl J. Greenblatt, trading as G & W Laboratories, Jersey City, N. J.

ALLEGED SHIPMENT: Between the approximate dates of January 1 and June 9, 1950, from the State of New Jersey into the State of New York.

LABEL, IN PART: "Formula—Phosphorus Ext. Nux Vomica ¼ gr. (Strychnine 1/55 gr.) Ext. Damiana * * * 24 Tablets Beatsol Rectifiers For Both Sexes," "Beatsol Drawing Salve * * * Formula—Rosin Ichthammol Petrolatum White Wax," and "Beatsol Earache Outfit * * * Ether 45 Min. Alcohol 20 Min. Oil of Camphor * * * Complete Outfit Consists of Cotton Rolls and Beatsol Earache Liquid."

NATURE OF CHARGE: *Beatsol Rectifiers.* Misbranding, Section 502 (a), the label statements "Rectifiers For Both Sexes * * * Lost vitality Impotence Exhausted Nervous Weakness" were false and misleading. The statements represented and suggested that the article would be efficacious in the treatment of lost vitality, impotence, exhaustion, nervousness, and weakness, whereas the article would not be efficacious in the treatment of such conditions. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in that the article contained strychnine; and its labeling failed to warn that no more than the recommended dosage should be taken and that the use by elderly persons of a drug containing strychnine may be dangerous.

Beatsol Drawing Salve. Misbranding, Section 502 (a), certain statements on the labels of the article were false and misleading. The statements represented and suggested that the article would be efficacious in the treatment of boils, carbuncles, ulcers, felons, and similar conditions implied by the abbreviation "etc.," whereas the article would not be efficacious in the treatment of such conditions.

Beatsol Earache Liquid. Misbranding, Section 502 (a), certain statements on the labels of the article were false and misleading. The statements repre-

sented and suggested that the article would be efficacious to relieve pain and aches in the ear and buzzing and water in the ear and to soften wax in the ear, whereas the article would not be efficacious for such purposes.

DISPOSITION: November 7, 1952. The defendant having entered a plea of nolo contendere to counts 1, 2, and 3, which related to the *Beatsol Rectifiers*, and a plea of guilty to counts 4, 5, and 6, which related to the *Beatsol Drawing Salve* and the *Beatsol Earache Liquid*, the court imposed a fine of $100 on each of the first three counts of the indictment and a fine of $200 on each of the remaining three counts, a total fine of $900.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3830. Adulteration and misbranding of imitation Premarin tablets. U. S. v. Max Lippmann. Plea of nolo contendere. Fine, $500. (F. D. C. No. 32695. Sample No. 23101–L.)

INFORMATION FILED: March 13, 1952, District of New Jersey, against Max Lippmann, Paterson, N. J.

INTERSTATE SHIPMENT: On or about April 4, 1950, from the State of New York into the State of New Jersey.

ALLEGED VIOLATION: Between the approximate dates of April 4 and August 31, 1950, while a number of tablets of the drug were being held for sale after shipment in interstate commerce, the defendant caused a number of tablets to be repackaged into envelopes and labeled and marked, in part, as "Premarin Tablets 1.25 mg.," and to be sold and delivered to various retail druggists, which acts resulted in the repackaged tablets being adulterated and misbranded.

NATURE OF CHARGE: Adulteration Section 501 (c), the strength of the repackaged tablets differed from, and their quality fell below, that which they purported and were represented to possess. The repackaged tablets purported to be and were represented as 1.25 mg. Premarin tablets, manufactured by Ayerst, McKenna & Harrison, Ltd., New York, N. Y., which tablets contain conjugated water-soluble estrogens equivalent to 1.25 mg. of sodium estrone sulfate, whereas the repackaged tablets were not 1.25 mg. Premarin tablets and did not contain conjugated water-soluble estrogens; and Section 501 (d) (2), a drug containing no conjugated water-soluble estrogens had been substituted for 1.25 mg. Premarin tablets, a drug which contains conjugated water-soluble estrogens.

Misbranding, Section 502 (a), the statement "Premarin Tablets 1.25 mg." on the label of the repackaged tablets was false and misleading. The statement represented and suggested that the repackaged tablets were 1.25 mg. Premarin tablets, manufactured by Ayerst, McKenna & Harrison, Ltd., New York, N. Y., which tablets contain conjugated water-soluble estrogens equivalent to 1.25 mg. of sodium estrone sulfate, whereas the repackaged tablets were not 1.25 mg. Premarin tablets and did not contain conjugated water-soluble estrogens; and, Section 502 (i) (2), the repackaged tablets were an imitation of another drug in that such tablets resembled in outward appearance genuine 1.25 mg. Premarin tablets, and were labeled, sold, and distributed as genuine 1.25 mg. Premarin tablets containing conjugated water-soluble estrogens equivalent to 1.25 mg. of sodium estrone sulfate, which are manufactured by Ayerst, McKenna & Harrison, Ltd., New York, N. Y., but the re-

packaged tablets were not genuine 1.25 mg. Premarin tablets and did not contain conjugated water-soluble estrogens.

DISPOSITION: May 16, 1952. A plea of nolo contendere having been entered, the court imposed a fine of $500.

3831. Adulteration and misbranding of stilbestrol tablets. U. S. v. 233,700 Tablets * * *. (F. D. C. No. 32985. Sample No. 49041-L.)

LIBEL FILED: March 27, 1952, Eastern District of New York.

ALLEGED SHIPMENT: On or about January 21, 1952, by Nysco Laboratories, Inc., from Newark, N. J.

PRODUCT: 233,700 *stilbestrol tablets* at Long Island City, N. Y.

LABEL, IN PART: (Tin) "Stilbestrol Tablets 1.0 Mg. * * * Warning: This is an extremely dangerous and toxic drug. Improper use may result in severe and even fatal injury * * * Empire Chemical Co., Inc. New Brunswick, New Jersey."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Diethylstilbestrol Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard. (The standard provides that diethylstilbestrol tablets contain not less than 90 percent and not more than 110 percent of the labeled amount of diethylstilbestrol. Analysis showed that the article contained from 122 to 125 percent of the labeled amount.)

Misbranding, Section 502 (a), the label statement "Stilbestrol Tablets 1.0 Mg." was false and misleading as applied to the article, which contained from 1.22 to 1.25 mg. of diethylstilbestrol per tablet.

DISPOSITION: October 29, 1952. Default decree of condemnation and destruction.

3832. Adulteration and misbranding of male hormone tablets. U. S. v. 76 Boxes, etc. (F. D. C. No. 33289. Sample Nos. 32442-L, 32445-L, 32449-L.)

LIBEL FILED: June 12, 1952, Western District of Arkansas.

ALLEGED SHIPMENT: On or about March 28 and April 22, 1952, by Captivante Laboratories, from New York, N. Y.

PRODUCT: *Male hormone tablets.* 76 boxes, 31 boxes, and 161 boxes, each containing 60 tablets of the article at Hot Springs, Ark., in the possession of the Yale Pharmacal Co., together with a number of accompanying form letters commencing with "Confidentially this letter can change your whole life," "Personal private gland information for men only," "Dear Customer: We thank you for your recent order," and "Dear Customer: In checking our files," and a number of leaflets entitled "Request for progress report on your case" and "Discover new, safe, more effective combination of male sex hormones." Some of the form letters and leaflets were printed at New York, N. Y., and others were printed locally.

Analysis showed that each tablet of the article in the 76-box lot contained not more than 1.2 mg. of methyltestosterone and not more than a trace of ethinylestradiol.

LABEL, IN PART: (76-box lot) "Yale Testrex Male Sex Hormones 60 Tablets—Super-Strength (Double Potency) * * * Ingredients per tablet 5 mg. Methyl Testosterone with Ethinyl Estradiol .002," (31-box lot) "Yale Testrex

Male Sex Hormones 60 Tablets * * * Ingredients per tablet 2.5 mg. Methyl Testosterone with Ethinyl Estradiol .001," and (161-box lot) "Yale Testrex Male Sex Hormones 60 Tablets * * * Ingredients per tablet 2.5 mg. Methyl Testosterone with Ethinyl Estradiol .0025 mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article (all lots) differed from that which it purported and was represented to possess.

Misbranding, Section 502 (a), certain statements in the accompanying form letters and leaflets were false and misleading since the article (all lots) was not capable of fulfilling the promises of benefit stated and implied. The statements represented and suggested that the article would be effective to restore one's masculine drive, ambition, energy, and ability to do things one wants to do; that it would enable one to lead happier, more contented, and more forceful business and home lives; that it would be effective in rejuvenating men; that it would be effective to correct sex hormone deficiencies; that it would be effective in the treatment of the symptoms of the male change of life, such as aches and pains, tired out feeling, lack of desire to enjoy one's self, nervousness, fear, and frustration; that it would be effective to restore prematurely old men to useful, active lives; that use of the article would result in new vigor, new vitality, increased virility, added strength, and new energy; that the article would give one a new lease on life, enable weak effeminate men to become more masculine, restore waning physical and mental powers in men, and enable aging men to recapture the pleasures of their youth.

The article was adulterated and misbranded when introduced into and while in interstate commerce, and it also was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 23, 1952. Default decree of condemnation and destruction.

3833. Adulteration and misbranding of Livocomp capsules. U. S. v. 48 Bottles, etc. (F. D. C. No. 33346. Sample No. 4273-L.)

LIBEL FILED: July 11, 1952, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about May 9, 1952, by Nysco Laboratories, Inc., from Long Island City, N. Y.

PRODUCT: *Livocomp capsules.* 48 bottles, each containing 100 capsules, of the product at Richmond, Va. Examination showed that it contained 74 percent of the declared amount of vitamin B_1.

LABEL, IN PART: (Bottle) "100 Capsules No. 1001 Livocomp For secondary anemia due to iron deficiency * * * Each Capsule Contains: * * * Vitamin B-1 333 USP Units 1 MDR."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, "Each Capsule Contains: * * * Vitamin B-1 333 USP Units 1 MDR."

Misbranding, Section 502 (a), the label statement "Each Capsule Contains: * * * Vitamin B-1 333 USP Units 1 MDR" was false and misleading as applied to the article, which contained less than the declared amount of vitamin B_1.

The libel alleged also that a quantity of Improcal tablets was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: September 9, 1952. Default decree of condemnation and destruction.

3834. Adulteration and misbranding of adhesive bandages. U. S. v. 60 Gross * * *. (F. D. C. No. 32569. Sample No. 26078–L.)

LIBEL FILED: February 29, 1952, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about January 15, 1952, by Supreme First Aid Co., Inc., from New York, N. Y.

PRODUCT: 60 gross of *adhesive bandages* at Philadelphia, Pa.

LABEL, IN PART: "Supreme Sterilized Handy Adhesive Bands."

NATURE OF CHARGE: Adulteration, Section 501 (b), the quality of the product fell below the standard set forth in the United States Pharmacopeia since it was not sterile.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading since the product was contaminated with living micro-organisms.

DISPOSITION: August 20, 1952. Default decree of condemnation and destruction.

3835. Adulteration and misbranding of adhesive bandages. U. S. v. 3 Cartons, etc. (F. D. C. No. 33053. Sample No. 12613–L.)

LIBEL FILED: April 7, 1952, Middle District of Tennessee.

ALLEGED SHIPMENT: On or about February 21, 1952, by Supreme First Aid Co., Inc., from New York, N. Y.

PRODUCT: 3 cartons, each containing 10 gross, and 1 carton, containing 2 gross, of *adhesive bandages* at Nashville, Tenn. Examination showed that the product was not sterile but was contaminated with viable micro-organisms.

LABEL, IN PART: "Supreme Handy Adhesive Bands Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Adhesive Absorbent Bandage," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since it was not sterile.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading as applied to the article, which was not sterile.

DISPOSITION: September 2, 1952. Default decree of destruction.

3836. Adulteration and misbranding of clinical thermometers. U. S. v. 118 Dozen * * *. (F. D. C. No. 32398. Sample No. 19297–L.)

LIBEL FILED: January 2, 1952, Southern District of Iowa.

ALLEGED SHIPMENT: On or about October 24, 1951, by Ideal Thermometer Co., Inc., from Brooklyn, N. Y.

PRODUCT: 118 dozen *clinical thermometers* at Iowa City, Iowa. Examination of 24 thermometers showed that 2 failed to meet the test for accuracy; that 3 failed to meet the test for hard shakers; that 5 failed to meet the entrapped gas test; that 5 had marks wider than the intervening spaces; and that 11 had the arrow pointing to 98.8° or 99.0°.

LABEL, IN PART: "Colorfast Brand Clinical Thermometers."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements appearing in a circular contained in a package of 2 dozen thermometers were false and misleading since the article did not conform to the specifications set forth in CS1-42 Bureau of Standards' Commercial Standard: "This certificate guarantees you that the manufacturer hereby certifies that the enclosed registering clinical thermometer will meet all the requirements and tests as specified in Clinical Thermometer Commercial Standard No. CS–1–42."

Disposition: March 18, 1952. Ideal Thermometer Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the article be released under bond, conditioned that it be salvaged by segregation of the good thermometers from the defective. Approximately 944 thermometers were found defective and were destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE *

3837. Misbranding of Alpha Formula and Tone physiological salt tablets. U. S. v. Frank J. Unger (Van Raye Laboratories). Plea of nolo contendere. Fine, $1,000. (F. D. C. No. 32724. Sample Nos. 11549–L, 11550–L.)

Information Filed: October 10, 1952, Northern District of Ohio, against Frank J. Unger, trading as the Van Raye Laboratories, Cleveland, Ohio.

Alleged Shipment: On or about October 2, 1951, from the State of Ohio into the State of Tennessee.

Product: Analysis disclosed that the *Alpha Formula* was a black, aromatic aqueous liquid containing chiefly epsom salt, sulfur, and plant extractives, including emodin bearing drugs and a trace of alcohol, and that the *Tone physiological salt tablets* contained chiefly sodium chloride and small amounts of the chlorides of potassium, calcium, and magnesium, with reducing sugar and a small amount of phosphate.

Nature of Charge: *Alpha Formula.* Misbranding, Section 502 (a), certain statements in a circular entitled "The Alpha and Tone Course," which accompanied the article, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for ailments associated with toxemia, alimentary or otherwise, which show symptoms of incidental, habitual, or secondary constipation, and blood salt deficiencies; that it was an adequate and effective treatment for anemia, arthritis, sciatica, neuritis, headache, nervousness, and high blood pressure; and that it was an adequate and effective treatment for stomach, liver, kidney, intestine, skin, and blood troubles, and many other ailments. The article was not an adequate and effective treatment for the purposes and conditions represented.

Tone physiological salt tablets. Misbranding, Section 502 (a), certain statements in the circular entitled "The Alpha and Tone Course," which accompanied the article, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment in reducing blood salt deficiencies due to colds and fevers; that it was an adequate and effective treatment for sinus, perverted or ravenous appetite, overweight, impairment of sense of taste, Addison's and other adrenal cortex deficiencies, lobar pneumonia, pernicious vomiting, severe burns, diabetic acidosis, and other

*See also Nos. 3829–3836.

conditions in which blood salt is deficient; that it was an adequate and effective treatment for fatigue, weakness, depression, twitching, cramps, convulsions, stroke, poor blood circulation, and difficult breathing due to exposure to excessive heat and excessive perspiration; that it would enable the user to stop the tobacco habit; that it was an adequate and effective treatment for ailments associated with toxemia, alimentary or otherwise, which show symptoms of incidental, habitual, or secondary constipation, and blood salt deficiencies; that it was an adequate and effective treatment for anemia, arthritis, sciatica, neuritis, headache, nervousness, and high blood pressure; and that it was an adequate and effective treatment for stomach, liver, kidney, intestine, skin, and blood troubles, and many other ailments. The article was not an adequate and effective treatment for the purposes and conditions represented.

DISPOSITION: October 31, 1952. A plea of nolo contendere having been entered, the court imposed a fine of $1,000.

3838. Misbranding of Somaca. U. S. v. 75 Bottles, etc. (F. D. C. No. 31774. Sample Nos. 23640–L, 37576–L.)

LIBEL FILED: On or about October 22, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about August 31, 1951, by Garrett Laboratories, Inc., from Clifton, N. J.

PRODUCT: 75 3-ounce bottles of *Somaca*, 1,500 copies of a leaflet entitled "This Can Happen To You," 700 copies of a letter entitled "My Dear Friend," and 200 copies of a letter entitled "Dear Friend" at New York, N. Y.

LABEL, IN PART: "Net Wgt. 3 ounces SOMACA * * * Active Ingredients Belladonna Extract Powder Each level teaspoonful of Somaca contains about 0.1 mg. Belladonna alkaloids. Sodium Bicarbonate Calcium Carbonate Magnesium Oxide John Peck Laboratories, Inc."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the product, namely, in the leaflets entitled "This Can Happen To You" and in the letters entitled "My Dear Friend" and "Dear Friend," were false and misleading since the article would not be effective in the treatment of ulcers of the digestive tract, as claimed in the labeling.

DISPOSITION: November 21, 1951. Default decree of condemnation and destruction.

3839. Misbranding of Foley Quit-Its throat lozenges. U. S. v. 243 Vials * * *. (F. D. C. No. 32577. Sample No. 10628–L.)

LIBEL FILED: March 6, 1952, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about January 11 and February 6, 1952, by Foley & Co., from Chicago, Ill.

PRODUCT: 243 vials of *Foley Quit-Its throat lozenges* at Milwaukee, Wis.

LABEL, IN PART: (Vial) "Fifteen Foley Quit-Its Antibiotic-Anesthetic Throat Lozenges * * * Each lozenge contains 1 mg. of tyrothricin, 7.5 mg. of benzocaine and ½ grain of ammonium chloride."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a leaflet entitled "Is Your Face Ever Red," which was enclosed in the carton with each vial, were false and misleading. These statements represented and suggested that the product would be effective in checking, combating, helping to overcome, and preventing throat infections, in protecting against reinfection, and in getting at the cause most often responsible for the condition; that

the tyrothricin contained therein was more effective than penicillin in destroying mouth bacteria; that it would destroy the bacteria that bring on clogged and runny nose and sore throat; and that it would check cough and bronchial congestion and secondary infections and thereby frequently abort colds. The product was not capable of producing the results claimed.

DISPOSITION: May 7, 1952. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

3840. Misbranding of U. S. Stock Food Tonic, U. S. Pheno-Min-Ton, U. S. Poultry Food Tonic, U. S. Poultry Worm Powder, and U. S. Stock Compound. U. S. v. United States Food Co. and Edgar Archer. Pleas of guilty. Joint fine of $350 imposed. (F. D. C. No. 31305. Sample Nos. 72148–K, 84977–K, 9319–L, 9325–L, 9330–L, 10759–L, 10760–L.)

INFORMATION FILED: March 13, 1952, Southern District of Ohio, against the United States Food Co., a partnership, Cambridge, Ohio, and Edgar Archer, a partner.

ALLEGED SHIPMENT: Within the period from on or about November 1, 1949, to on or about October 17, 1950, from the State of Ohio into the State of Indiana.

LABEL, IN PART: "U. S. Stock Food Tonic * * * Guaranteed Analysis Calcium (Ca), not less than 12.00% Phosphorus (P), not less than 2.00% Salt (NaCl), not more than 19.65% Iodine (I), not less than 0.02% Ingredients: Quassia, Ginger, Gentian Root, Blood Root, American Wormseed, Epsom Salt, Sulphur, Charcoal, Salt, Flaxseed and Ground Grain Screenings Meal 7.4%, Calcium Carbonate from Powdered Limestone, Soft Phosphate with Colloidal Clay, Steamed Bone Meal, Rock Phosphate, Sulphate of Iron, Foenugreek, Manganese Sulphate 0.03%, Potassium Iodide and Irradiated Dry Yeast," "U. S. Pheno-Min-Ton A Special Mineral-Vegetable Powder for Sheep Composed of Phenothiazine, U. S. Stock Food Tonic, and Salt," "U. S. Poultry Food Tonic * * * Guaranteed Analysis Calcium (Ca), not less than 15.00% Phosphorus (P), not less than 1.55% Salt (NaCl), not more than 10.00% Iodine (I), not less than 0.02% Ingredients: Quassia, Ginger, Iron Oxide, Sulphur, Calcium Carbonate from Powdered Limestone, Salt, Sulphate of Iron, Flaxseed and Ground Grain Screenings Meal 17.5%, Soft Phosphate with Colloidal Clay, Steamed Bone Meal, Rock Phosphate, Epsom Salt, Foenugreek, Manganese Sulphate 0.03% and Potassium Iodide," "U. S. Poultry Worm Powder * * * Powdered Areca Nut, American Wormseed, Iron Sulphate, Quassia, Sulphur, Epsom Salts, Tobacco Powdered," and "U. S. Stock Compound A Mineral-Vegetable Compound."

Accompanying one shipment of the *U. S. Stock Food Tonic* was additional labeling entitled "Words of Praise From Users," "Prize Winners at the Illinois, Indiana and Kentucky State Fairs," "Special Directions. How to Feed the U. S. Preparations," "Why U. S. Stock Food Tonic Gives Stockmen So Much More Weight in Service and Profit Than Powders Containing Minerals Only," and "How to Feed U. S. Stock Tonic To All Livestock." Accompanying the other shipment of the *U. S. Stock Food Tonic* was additional labeling entitled "U. S. Helps Make Grand Champion" and "How to Feed U. S. Stock Tonic To All Livestock."

Accompanying the *U. S. Pheno-Min-Ton* was additional labeling entitled "Co-operate With Nature and Succeed With Sheep."

Accompanying the *U. S. Poultry Food Tonic* was additional labeling entitled "Directions for Feeding U. S. Poultry Food Tonic."

Accompanying the *U. S. Stock Compound* was additional labeling entitled "Special Directions. How to Feed the U. S. Preparations," "How to Feed U. S. Stock Tonic To All Livestock," "Feed U. S. and Get Your Hogs to Market Sooner," "Representatives of Two Kingdoms," "Prize Winners at the Illinois, Indiana and Kentucky State Fairs," "Why U. S. Stock Food Tonic Gives Stockmen So Much More * * *," "Some of the Fine Hereford Cows and Calves on the United States Stock Food Farm," "For Scours in Calves," "How Much Pork Should a Bushel of Corn Produce?" "U. S. Helps Make Grand Champion," "Symptoms of 'Necrotic Enteritis' or Rot Gut," "Words of Praise From Users," and "The Danger of Worms, and the Dangers Caused by Improper Treatment of Worms."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading. These statements represented and suggested that:

The U. S. Stock Food Tonic (1 shipment) would remove all worms from livestock, prevent worm infestation, and control worms in livestock, would keep animals healthy and restore them to a normal healthy condition regardless of condition before using, would be effective in the prevention and treatment of bloat in cattle, in the treatment of bowel trouble in hogs and scours in calves, and in the prevention of necro in swine, would cause noneating cows to eat, (remaining shipment) would remove worms from swine, would control worms in swine, and keep swine free from worms, would keep hogs in perfect condition, would remove and control stomach worms in sheep, and would prevent scours in calves.

The U. S. Pheno-Min-Ton would effectively fight and control all species of worms in sheep, would promote better health in sheep, would save feed, would restore sheep to a normal healthy condition, and would build blood and build up the system in sheep.

The U. S. Poultry Food Tonic would cause hens to lay more eggs, would keep poultry in a healthy condition, and would prevent diseases of fowls, such as cholera and roup.

The U. S. Poultry Worm Powder would be effective against all species of worms in poultry.

The U. S. Stock Compound would remove all worms from livestock, prevent worm infestation and control worms in livestock, would restore animals to a normal healthy condition regardless of condition before using, would prevent and treat bloat in cattle, would be an effective treatment for bowel trouble in hogs, scours in calves and pigs, and swine flu, would cause noneating cows to eat, would prevent necro in swine, was an intestinal antiseptic, was a useful medicine for ephemeral fevers, was an effective treatment for jaundice caused by inflammation of the liver, gallstones, weakening diseases such as influenza or distemper, liver abscesses, and any disorder of the liver, was beneficial for respiratory diseases characterized by difficult breathing and accompanied by a wheezing sound, was beneficial for coughs, was a febrifuge and alterative, would cool the blood, was valuable in influenza, pneumonia, and most febrile inflammatory disorders, was a diaphoretic and resolvent, was a blood purifier, would strengthen the stomach, was a tonic and astringent, was of value in cases of weakness, want of condition, looseness of the bowels, swelling of the legs, body, sheath, and breast, would improve and add richness to the blood and give tonicity and health to the fibrous, serous tissue, would restore and prevent effusions in pleuropneumonia of cattle, was of value where the power of life is low and depressed, and was an effective treatment for red water

in cattle, bleeding internally in all animals, dysentery, purpura, scarlatina, and debilitating diseases generally.

The articles would not be effective for the purposes represented and suggested.

DISPOSITION: April 8, 1952. Pleas of guilty having been entered, the court imposed a fine of $350 against the defendants jointly.

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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3841–3860

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *May 4, 1953.*

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DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3841. Misbranding of pentobarbital sodium capsules, sulfathiazole tablets, and penicillin tablets, and conspiracy to violate the laws of the United States. U. S. v. L. Samuel Kilbee (Imperial Pharmacy), John S. Bernreuter, Irvin M. Seay, and Roosevelt F. Mills. Pleas of nolo contendere by L. Samuel Kilbee, John S. Bernreuter, and Irvin M. Seay, and plea of not guilty by Roosevelt F. Mills. L. Samuel Kilbee fined $500 and John S. Bernreuter and Irvin M. Seay each fined $100. Roosevelt F. Mills tried to a jury; verdict of guilty on 2 counts charging aiding and abetting violation of Section 301 (k) and verdict of not guilty on 1 count charging conspiracy to violate the laws of the United States; fine, $300. (F. D. C. No. 30020. Sample Nos. 1150–K, 1152–K, 1156–K, 1255–K, 1586–K.)

INFORMATION FILED: May 3, 1951, Southern District of Florida, against L. Samuel Kilbee, trading as the Imperial Pharmacy, at Jacksonville, Fla., John S. Bernreuter and Irvin M. Seay, pharmacists employed by the Imperial Pharmacy, and Roosevelt F. Mills, a physician.

INTERSTATE SHIPMENT: From the States of Georgia and New Jersey into the State of Florida, of quantities of *pentobarbital sodium capsules*, *sulfathiazole tablets*, and *penicillin tablets*.

ALLEGED VIOLATION: On or about March 28 and 31, April 8, and June 16 and 21, 1949, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded. L. Samuel Kilbee was included as a defendant in each of the five counts involving sale of the drugs, and John S. Bernreuter was joined in four of such counts and Irvin M. Seay in one of such counts, and charged with the violations involved in those counts.

The information charged further that prior to the sales of the *sulfathiazole tablets* and the *penicillin tablets* (counts 4 and 5), Roosevelt F. Mills, a physician, furnished to L. Samuel Kilbee, at the Imperial Pharmacy, physician's prescription forms, which bore the signature in ink of Roosevelt F. Mills, and also the following printed matter: "Reg. No. 7243 Dr. R. F. Mills Physician and Surgeon 600 W. Ashley, Corner Broad Jacksonville, Fla. Office Hours: 10–2 & 6–8:30 P. M. Phones: Office 4–2244 Residence 4–2498 Patient's Name _____ Date _____ Address _____ Imperial Pharmacy Cor. Broad And Ashley Sts. Jacksonville Florida Phone 4–2159";

That the forms were furnished by Roosevelt F. Mills for the purpose of L. Samuel Kilbee filling out such forms and causing them to be filled out, and dispensing and causing drugs to be dispensed under such forms;

That John S. Bernreuter at the time of the sale involved in count 4 filled in one of the forms with the following: "William J. Barber 6/21/49 Post Office Box 711 Tablets Sulfathiazole 7.7 Gr. Sig. Two Tablets every 4 hours 398614 2.50 J. S. B." and dispensed the tablets in a vial labeled in part: "Imperial Pharmacy * * * #398614 Dr. Mills William J. Barber Two Tablets Every four hours 6/21/49 J. S. B.";

That Irvin M. Seay at the time of the sale involved in count 5 filled in one of the forms with the following: "Oscar Hartley 6/16/49 Penicillin Tabs 50,000 U #12 Sig Tab ii q 4 h. 398588 $3.50" and dispensed the tablets

in a box labeled, in part, "Imperial Pharmacy * * * 398588 Dr. Mills Two every 4 hours 6/16/49";

That the act of Roosevelt F. Mills in furnishing the prescription forms signed by him for the purposes stated above, aided and abetted L. Samuel Kilbee, John S. Bernreuter, and Irvin M. Seay in their violations of Section 301 (k).

The information alleged further, in count 6, that Roosevelt F. Mills, L. Samuel Kilbee, John S. Bernreuter, and Irvin M. Seay, combined, conspired, confederated, and agreed, together and with each other, to violate Section 301 (k) of the Federal Food, Drug, and Cosmetic Act;

That it was a part of the conspiracy that the defendants would dispense and cause to be dispensed, without labeling bearing adequate directions for use, *sulfathiazole tablets* and *penicillin tablets* which had been shipped in interstate commerce into the State of Florida and were being held for sale after such shipment;

That in pursuance of the conspiracy, at a time prior to the sales alleged in counts 4 and 5, Roosevelt F. Mills furnished to L. Samuel Kilbee, at the Imperial Pharmacy, Jacksonville, Fla., a number of physician's prescription forms hereinbefore described;

That in further pursuance of the conspiracy, and to effect the objects thereof, L. Samuel Kilbee, Irvin M. Seay, and John S. Bernreuter filled out and caused to be filled out the prescription forms for *sulfathiazole tablets* and *penicillin tablets*, respectively, hereinbefore referred to.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged *pentobarbital sodium capsules* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents. Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (f) (1), the repackaged *pentobarbital sodium capsules* failed to bear labeling containing adequate directions for use.

Misbranding, Section 502 (b) (2), the repackaged *sulfathiazole tablets* and *penicillin tablets* failed to bear labels containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the former failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the latter failed to bear a label containing the common or usual names of each active ingredient of the drug; and, Section 502 (f) (1), both failed to bear labeling containing adequate directions for use. Further misbranding, Section 502 (f) (2), the labeling of the repackaged *sulfathiazole tablets* bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: February 8, 1952. A plea of nolo contendere having been entered by L. Samuel Kilbee, the court found him guilty on all counts and fined him $500. Pleas of nolo contendere having been entered by John S. Bernreuter and Irvin M. Seay, the court found the former guilty on counts 1, 2, 3, 4, and 6 and the latter guilty on counts 5 and 6, and imposed fines of $100 against each.

A plea of not guilty having been entered by Roosevelt F. Mills, he was tried to a jury on February 7 and 8, 1952. At the conclusion of the trial, the court delivered the following charge to the jury:

The COURT. "Now, Mrs. Candito and Gentlemen:

"You have heard the testimony in this case and the argument of counsel, both for the United States and for the defendant. It becomes, then, the duty of the Court to instruct you as to the law applicable to the case. You are tired, I am tired, I guess we are all tired, and I say that, because I don't want you to let that interfere with your giving careful attention to what I have to say and giving careful consideration to the verdict in this case. It is important to the government and it is important to the defendant.

"The defendant in this case, as you know, has entered a plea of not guilty to the three counts of this information which concern him, Count Four, Five and Six. The effect of that plea of not guilty is to deny every material allegation in the information, or those counts of it, and put on the government the burden of proving his guilt beyond and to the exclusion of a reasonable doubt. If the government has failed as to those three counts, or any one of them, to prove the material allegations thereof beyond and to the exclusion of every reasonable doubt, then it is your duty to acquit the defendant, or to acquit him as to such counts as you find the government has failed to make proof beyond a reasonable doubt concerning.

"A reasonable doubt is a doubt naturally arising from the evidence, or lack of evidence. As the words import, it is a doubt conforming to reason, a doubt for which you can give a reason, or a doubt which a reasonable man would entertain. A reasonable doubt is that state or condition of the case which, after a full and fair consideration and comparison of all the evidence, leaves your mind in such condition that you cannot say that you feel an abiding conviction to a moral certainty of the truth of the charge.

"The defendant in this case, as in all criminal cases, is presumed to be innocent. This presumption of innocence accompanies the defendant and abides with him through every stage of the trial as to every material allegation of the indictment; and until your minds are convinced by the evidence beyond and to the exclusion of every reasonable doubt that he is guilty of the offense charged against him. But when your minds aren't so convinced of the guilt of the accused beyond and to the exclusion of every reasonable doubt, then that presumption of innocence ceases.

"It is on the evidence, and that alone, that you are to try the defendant. You, as jurors, under your oaths are carefully, calmly, fairly, and dispassionately to consider all the evidence in the case; and from such evidence and the law as given to you by the Court, you are to arrive at your verdict. It is your province and yours alone to pass on the disputed issues of fact in the case. It is the Court's province to give you the law in charge which you are to apply to the facts as you find them.

"You are not to be swayed from the performance of this duty by prejudice, sympathy, or any other sentiments, but you must try the case fairly and impartially on the evidence—and I emphasize that you are the sole judges of the evidence; and anything I may have to say to you by way of comment on the evidence is advisory only. The responsibility is yours to decide the question of fact involved here. I might further caution you that you are not to understand or infer from any ruling that I may have made in the course of the trial with regard to the evidence, anything I may have had to say to counsel for either side regarding the admissibility of evidence, or in ruling in any way in the case, you are not to understand any of those as being a personal opinion on my part as to the guilt or innocence of the defendant. That is just matter arising in the administration of the trial.

"You are the judges of the evidence, the weight of the evidence, and the credibility of the witnesses who have testified before you. If there is a conflict in the testimony before you, you must reconcile it, if you can, so as to make all the witnesses speak the truth, but if you cannot reconcile such a conflict, you may believe or disbelieve any witness or witnesses that you may or may not consider them entitled to credit, and if you disbelieve any witnesses, you have the right to ignore his or her testimony in making up your verdict,

although you should not captiously or capriciously disregard the testimony of any witness.

"In weighing the testimony of any witness, you should consider his apparent intelligence or want of intelligence, his relationship to the parties in the case, his interest, if any, in the result of the case, his bias or prejudice, if any, for or against the parties in the case, his appearance on the witness stand and his manner of testifying, his apparent frankness and candor, or want of frankness and candor in testifying, the reasonableness or unreasonableness of his testimony, the circumstances surrounding the witness at the time concerning which he testified, and the means and opportunity of his knowing the facts about which he testified, and all the other evidence in the case tending to corroborate or to contradict his testimony.

"In considering or weighing the evidence in this case, you should use the same judgment, reason, common sense, and general knowledge of men and affairs that you use in your everyday business life.

"Now, the defendant in a criminal case has the right to take the stand and testify in his own behalf. If and when he does so, his testimony goes to you the same as the testimony of any other witness in the case, and is to be weighed and considered by you according to the same rules—that is, the rules we have just been going over.

"Now, as to the allegations of the Fourth, Fifth, and Sixth Counts of this information which we are concerned with here, I may say that the stipulation which was read to you in the beginning takes away the necessity of proof of a good deal of those matters. It was stipulated that the drugs were shipped in Interstate commerce, that they were delivered to the Imperial Pharmacy, that they were in the containers as shown on those photostats, and that the containers were labeled as is shown, and that the labels were similar to the photostats. That is the first one, the one with the sulfathiazole, and the other one potassium G. penicillin, or penicillin potassium G—whatever it was. You remember that. There is no dispute about the drugs being in interstate commerce. Don't give yourselves any concern over that, because it is the law that they are in interstate commerce until they reach the ultimate consumer. In other words, if they came from some drug house in New York, from there to the Imperial Pharmacy, and from there to the person or persons who consumed it, all the time they were in interstate commerce, so that consideration is out of the case; you don't need to consider it. That is as to all counts of this.

"Now, going on down into the Fourth Count, that is the Count as to the sulfathiazole, which alleges that the defendant Mills aided and abetted the misbranding of this drug by furnishing the blank forms, the blank signed prescription forms to Kilbee, to the former defendant Kilbee, for the purpose of Kilbee filling them out or causing them to be filled out, and dispensing, or causing to be dispensed drugs under the prescription form.

"The next important allegation of this Fourth Count is that Bernreuter on June 21, 1949, or at some date—you don't have to be concerned with the exact date, as I think I have had occasion to charge most of you before, if the date is within three years prior to the filing of the information; so all the dates here are within the time. At any rate, Bernreuter admitted this sale to Barber, and filled in the blank form that had been previously furnished by Dr. Mills, and that this act of removal, repacking and disposal of these tablets resulted in their being misbranded within the meaning of Section 352 B of the Food and Drug Act; 21 US Code 352.

"Now, very nearly the same charge is made in the Fifth Count with respect to penicillin being sold to Oscar Hartley, by Irvin M. Seay, and that it was done by filling in this blank prescription form which has previously been furnished to Kilbee by Mills.

"The law requires that the labeling of a drug must bear adequate directions for use, otherwise it is misbranded, and that is the charge here: That it is misbranded. Now, regulations adopted having all the force and effect of law, exempt drugs from bearing on their label adequate directions for use if the drug bears the label, 'Caution: To be dispensed only by or on the prescription of a physician.' These same regulations provide that these exemptions shall expire—in other words, as if no exemptions existed, unless it bears 'Caution: To be only dispensed by a physician or by a physician's prescription.'

"Now, there is no dispute under the stipulation as to the label that the—both drugs involved here, sulfathiazole and penicillin, were received by the Imperial

Pharmacy, when they were received, both as was stated. The evidence also stated that these drugs, when sold by the Imperial Pharmacy—that is, one sold to Barber, in the Fourth Count, and the penicillin in the Fifth Count, sold to Barber in the Fifth Count, bear the instruction, 'two every four hours.' Standing alone, such instructions for use of those drugs do not constitute adequate directions for use. However, if you find—and this is a matter that you have got to decide—if you find that the drugs were sold in response to valid and legitimate prescriptions of the doctor, then the drugs would bear adequate directions for use. If you find, on the other side, that the drugs were sold by the Imperial Pharmacy without valid and lawful prescription, then you must find that the drugs were misbranded at the time of the sale.

"Now, I further instruct you that a valid prescription—you will recall the testimony of Dr. Husa as to what a valid prescription was—that a valid prescription means directions to a druggist by a doctor for a particular medicine to be put up for a patient to be used at a particular time and in a particular way—the furnishing of the blank sheet of paper on a prescription form with the doctor's signature on it is not a valid prescription, it couldn't be; and, therefore, as to this Fourth and Fifth Count—if the drugs were sold without any contact between the doctor and the patient, to just walk in and buy them, as testified here, and it is up to you to decide whether that testimony is true—just walk in and buy them, and no connection between the doctor and the patient, and the prescription form to be filled in later, why, then, it wasn't sold on a valid prescription.

"Now, if it was sold, if it was dispensed by the druggist after telephone conversation with the doctor, and the doctor told the druggist to dispense the drugs, it is my view that that is a valid prescription, that there can be a valid dispensing on a valid prescription by the doctor telling the druggist to give the patient so and so, without anything further. So it is up to you to decide as to those Fourth and Fifth Counts, what actually happened, how the drugs were dispensed, and whether it was by instructions of the doctor over the phone, or whether it was simply by the druggist filling in these blank prescriptions. Now, if it was done in the latter way, which you must find, as I told you, beyond a reasonable doubt, before you would be warranted in convicting under the Fourth and Fifth Counts—if it was done in that way, then the druggist that dispensed it would be guilty of misbranding by not having sold on a valid prescription, and misbranding these drugs; and the United States statutes provide that 'whoever commits an offense against the United States or aids and abets, compels, commands, induces or procures its commission, is punishable as a principal.'

"Now, as to these Fourth and Fifth Counts, if you reach that point in your deliberations that you believe that these acts—that the druggist Seay, in one instance, and Bernreuter in the other, is guilty of selling these misbranded drugs, if you reach that point in your deliberations, you are required to determine whether or not the defendant here Mills, is guilty of aiding and abetting, since, as I just read, the statute provides that whoever aids and abets the commission of an offense is guilty as a principal. Specifically, did he aid and abet the dispensing of misbranded drugs by furnishing these blank prescriptions which I have told you wouldn't be any prescriptions at all. If he furnished those, so that the other men could sign them—and it is up to you to decide it, whether the government has proved it beyond and to the exclusion of every reasonable doubt from all the evidence—if he did, you can find the doctor guilty under the Fourth Count or Fifth Count or both, whichever you find that that proof has been made to.

"I think that that, perhaps, is sufficient discussion of those two Counts. To come down to the next Count, which charges a conspiracy between Mills, Roosevelt Mills, the physician, the owner of the drugstore, the operator of the drugstore, and Bernreuter and Seay, the two pharmacists, that they conspired to commit offenses against the United States; that is, violate the statute about misbranding drugs. Now, as far as proving the other two Counts, intent is not an element there; that is to say, if the doctor did actually aid or abet in the commission of the offenses by the druggists, as charged there in Four and Five, his intent is not material. However, in this conspiracy charge, this intent does come into it. The charge here is: That this conspiracy existed, and that it was to dispense or cause to be dispensed without labeling bearing adequate directions for the use, drugs misbranded in viola-

tion of the statute, the penicillin tablets and sulfathiazole tablets, and it is charged that the sale to Barber—no, the first overt act charged is the furnishing,—in the carrying out of the conspiracy, the charge of furnishing of blank forms of prescriptions signed by Mills and furnished by Mills to Kilbee. Then the second overt act charged is the Hartley sale, and the third overt act charged is the Barber sale.

"Now, if two or more persons conspire to commit on offense against the United States, and one or more of such conspirators do an act to effect the object of the conspiracy, each of the parties to the conspiracy shall be punished and so on. That is the statute under which conspiracy is charged. Conspiracy is the combination of two or more persons to accomplish by the united or concerted action a criminal or unlawful purpose, or to accomplish some lawful purpose by a criminal or unlawful means. The unlawful purpose charged here is the violation of these misbranding statutes in the regulations. When two or more persons agree together to do an unlawful act, when they combine to accomplish that by their united actions, a conspiracy is formed. It is formed when such a combination is entered into, and the offense is consummated when one or more of the parties to the conspiracy commit one or more of the overt acts charged in the indictment. It is not necessary that two or more persons meet together and enter into any explicit or formal agreement to form an unlawful scheme, to constitute a conspiracy; nor is it necessary that they should directly by words or in writing state what the unlawful scheme should be, nor detail the plans by which the unlawful scheme or combination should be effected. It is sufficient that two or more, in any amount or through any contrivance—that is, by a direct, implied, or inferred agreement amongst themselves—come to a mental understanding to accomplish a definite unlawful design. In other words, when an unlawful end is sought to be accomplished, and they work together in any way in the furtherance of the unlawful scheme, every one of such persons becomes a member of such conspiracy, although the part he is to take therein is a subordinate one, and is to be executed at a remote distance from the other conspirators. Proof of a definite plan or formal agreement by the conspirators can seldom be shown by direct evidence, and such proof is not necessary. It is as competent to prove an alleged conspiracy by circumstantial as by direct evidence. Indeed, the existence of a conspiracy is generally shown by circumstantial evidence, because an unlawful agreement or combination usually exists only in the minds of the conspirators, and such a mental state is not usually susceptible of direct proof, but must be gathered from circumstances shown in evidence. In order to establish proof of conspiracy, the circumstantial evidence, according to the facts and circumstances shown in evidence, must not only be consistent with guilt, but must be inconsistent with any other reasonable or rational hypothesis of innocence.

"While circumstantial evidence is equally available as direct evidence to prove the existence of conspiracy, mere suspicion or conjecture cannot take the place of evidence. Suspicion alone may not take the place of proof of guilt. If the facts and circumstances are as consistent with innocence as guilt, no conviction can properly be had.

"Of course, you may and should consider all the direct evidence along with the circumstantial evidence, and weigh it all together.

"Now, the conspiracy must be proven to exist beyond a reasonable doubt, and must be in existence at or prior to the commission of an overt act. If you find proof merely of an alleged overt act, without proof beyond a reasonable doubt of the conspiracy, then you should acquit this defendant as to the conspiracy count, the Sixth Count.

"And you further understand that before a conviction can be had of conspiracy, there must not only be this conspiring together that we have been talking about, but the formation of the conspiracy must be followed by the commission of one or more of the overt acts charged in the indictment, then, to effect the object of a conspiracy; for, otherwise, the conspiracy charged in the conspiracy count cannot be carried out. The overt acts need not be necessarily committed by this particular defendant. If you find that the government has proved the commission of one or more overt acts by other parties to the conspiracy in furtherance of the conspiracy—that is, one or more of the overt acts charged in the indictment. In other words, if the conspiracy was formed, then at the moment that the overt acts, or any one of

them were done to effect the continued existence of the conspiracy, and to effect the object of the conspiracy, at that moment, criminal responsibility for the intents charged in this Sixth Count was consummated, by these acts or any of them done to effect the object of the conspiracy. Though certain acts were done by only one party this would bind each and every party to the conspiracy, and such act becomes the act of every party to the conspiracy.

"Now, evidence of the defendant's good character should be considered by you with the other evidence in the case, and may, in connection therewith, be sufficient to raise a reasonable doubt in your minds as to the defendant's guilt. Evidence of the defendant's good character is of the same category as other factual evidence, and must be considered by you in your deliberations, and may of itself be believed by you and create a reasonable doubt, where heretofore no reasonable doubt would exist.

"The defendants in this case, other than Dr. Mills, have pleaded nolo contendere, therefore are not being tried by you along with the defendant Mills. You are not to permit the fact that the other defendants have entered such a plea to have any connection; you are to consider only the charges for which he is now being tried before you.

"Now, I think that that is a sufficient discussion for the purposes of the evidence here. You are to weigh all the circumstances in evidence as to each count of the indictment—or the information—as you find it as they may apply, and reach a unanimous verdict. You understand all twelve of you must concur, and reach a unanimous verdict as to the guilt or innocence of the defendant. If you find he is guilty—after consideration and comparison of all of the evidence, if you find that the government has made out a case beyond and to the exclusion of a reasonable doubt as to one or more counts of the indictment—or the information—you say in your verdict: 'We, the Jury, find the defendant Roosevelt Mills guilty of the charge in count blank,' and specify which count of which you find him guilty.

"If the government has failed in its proof of any one or more of the counts of the information beyond a reasonable doubt, you find him not guilty, and you say in your verdict, 'We, the Jury, find the defendant Roosevelt Mills not guilty, so say we all.' And, as I say, your verdict must be unanimous. One of you must sign it as foreman, dated Jacksonville, Florida. You should select a foreman when you first go out, and let the foreman preside over your deliberations and sign the verdict.

"Are there any further objections, other than the objections in chambers, as to the charge?

"Are there any further objections you want to make?"

Mr. WALKER. "No, Your Honor."

Mr. ROTHSTEIN. "No, Your Honor."

The COURT. "Now, you are not concerned with the first three counts of this indictment. There's only four, five, and six———— it is an information; I keep calling that thing an indictment; it is an information signed by the United States Attorney. Take that, and the exhibits in.

"You may retire, then, for consideration of your verdict."

The jury having found the defendant, Roosevelt F. Mills, guilty on counts 4 and 5 involving the charge of aiding and abetting in the illegal sale of *sulfathiazole tablets* and *penicillin tablets* and not guilty on count 6 involving the charge of conspiracy to violate the laws of the United States, the court imposed a fine of $300.

3842. Misbranding of Seconal Sodium capsules. U. S. v. Frank C. Tuma (Tuma Drugs). Motions for dismissal of information and for bill of particulars denied. Plea of guilty. Fine of $300, plus costs. (F. D. C. No. 28104. Sample Nos. 42113–K to 42115–K, incl.)

INFORMATION FILED: January 17, 1950, Northern District of Illinois, against Frank C. Tuma, trading as Tuma Drugs, at Oak Park, Ill.

ALLEGED VIOLATION: On or about February 10, 14, and 23, 1949, while a number of *Seconal Sodium capsules* were being held for sale at Tuma Drugs after shipment in interstate commerce, the defendant caused a number of such

capsules to be repacked and sold without a physician's prescription, which acts resulted in the repackaged capsules of the drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the drug failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: On April 7, 1950, the defendant filed motions for dismissal of the information and for a bill of particulars, and on April 20, 1950, after consideration of the briefs of counsel, the court handed down the following decision:

The COURT: "I have read the briefs of the parties.

"This is a criminal action instituted by an Information charging the defendant with three separate violations of the Federal Food, Drug and Cosmetics Act.

"The Information is in three counts and charges that the defendant caused the misbranding of three distinct articles of drug while they were held for sale after shipment in interstate commerce.

"The first count charges that the defendant, 'on or about' February 14, 1949, caused the removal of a number of capsules of Seconal Sodium from a properly labeled bottle in which the drug had been shipped in interstate commerce and caused the capsules to be repackaged in a box which was sold to one William R. Price without a prescription.

"It further charges that the box in which the drug was repacked did not contain an accurate statement of the quantity of contents as required by the provisions of the Act (21 U. S. C. A. 352 (d) (2)); that it did not, as required by 21 U. S. C. A. 352 (d), bear the name and quantity or proportion of the derivative of barbituric acid, namely Seconal Sodium, of which the drug was composed, and it did not bear the statement 'Warning: May be habit forming'; and that it did not bear adequate directions for use as required by U. S. C. A. 352 (f) (1). It is alleged that causing the drug to be repacked in a box which did not bear the required labeling was an act which constituted a violation of 21 U. S. C. A. 331 (k).

"Counts II and III charge the defendant with similar violations of the Act which are alleged to have occurred on or about February 10, 1949, and February 23, 1949.

"The pertinent provisions of the Act are:

Section 331—

The following acts and the causing thereof are hereby prohibited: * * *
(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

Section 352—

A drug or device shall be deemed to be misbranded— * * *
(b) If in package form unless it bears a label containing * * *
(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Section 352—

A drug or device shall be deemed to be misbranded— * * *
(d) If it is for use by man and contains any quantity of * * * barbituric acid * * *; or any chemical derivative of such substance, which derivative has been by the Administrator, after investigation, found

to be, and by regulations designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning: May be habit forming."

Section 352—

A drug or device shall be deemed to be misbranded— * * *
(f) Unless its labeling bears (1) adequate directions for use.

"Defendant now moves in the alternative (1) to dismiss (2) for a bill of particulars.

"Defendant urges fifteen grounds for dismissal of the information:

"Grounds 1, 2, 3, 4—That the information and each count thereof is 'vague, indefinite and entirely insufficient to apprise the defendant of the charge which he is called upon to meet.'

"Grounds 5, 6, 9, 13, 14—That the language of the information in regard to the times of manufacture of the drugs, the times of interstate shipment and the times of intrastate transactions involving the drugs are also vague and indefinite and do not give the defendant sufficient information regarding the interstate shipments so as to allow him to prepare his defense.

"Grounds 7, 8, 10, 15—That the allegations to the effect that the defendant 'caused' certain actions to take place are vague and unsufficient to apprise the defendant of the charge he is called upon to meet.

"Ground 11—That the repackaging and selling of the capsules without a physician's prescription are immaterial, since they do not constitute a violation of any federal statute or regulation.

"Ground 12—That Count II is defective in that it fails to set forth the original label which accompanied the drug in interstate commerce.

"The Motion for a Bill of Particulars, the alternative motion, concerns itself with the following information: The dates of interstate shipment by the manufacturer; the dates of purchase by defendant; what acts were performed by defendant whereby he caused the drug to be repackaged and sold; whether defendant performed any acts personally in repackaging and selling; and, in regard to Count II, the legend printed on the label of container in which the drugs were shipped either to defendant or an intermediary.

"With reference to the motion to dismiss the information I am of the opinion it should be denied.

"All of the essential elements which are the gravamen of the crime are set forth with considerable particularity in the information, that is, the shipment of a drug in interstate commerce, and the subsequent disposal and misbranding of that drug. The essential allegation here is the fact of interstate shipment rather than when it was shipped. The Act is operative regardless of the length of time intervening between the shipment and the misbranding. In this regard I direct counsel's attention to the case of United States v. Sullivan, 332 U. S. 689.

"The allegations to the effect that the defendant 'caused' certain actions to take place is sufficient in the face of a motion to dismiss. As a matter of fact, these allegations are in precise language of the statute itself and I direct counsel's attention to Section 331.

"The fact that the legend of the original label is not set forth in Count II does not constitute a fatal defect. The language of that label is merely an evidentiary fact and is not an essential element of the crime nor does it prevent the defendant from preparing his case.

"As to the alternative motion for a bill of particulars, I am of the opinion that also should be denied.

"All the information sought in the bill is evidentiary in nature and has no reference to the defendant's ability to prepare his defense properly. No rule of criminal procedure requires that the prosecution lay bare its entire case to the defendant insofar as the evidentiary facts are concerned.

"Granting this motion would require the prosecution to do just that. Accordingly, both motions are hereby denied."

On May 23, 1950, the defendant entered a plea of guilty and the court fined him $300, plus costs.

3843. Misbranding of Seconal Sodium capsules. U. S. v. Glenn S. Shipp (The Chemist Shop). Plea of nolo contendere. Defendant sentenced to pay costs and to serve 60 days in jail. Sentence of imprisonment suspended and defendant placed on probation for 60 days. (F. D. C. No. 33731. Sample Nos. 16231–L to 16236–L, incl.)

INFORMATION FILED: December 16, 1952, District of Kansas, against Glenn S. Shipp, trading as The Chemist Shop, Independence, Kans.

ALLEGED VIOLATION: On or about December 5, 6, 13, 18, and 19, 1951, while a number of *Seconal Sodium capsules* were being held for sale at the Chemist Shop after shipment in interstate commerce, the defendant caused various quantities of the capsules to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use.

DISPOSITION: January 20, 1953. A plea of nolo contendere having been entered, the court sentenced the defendant to pay the costs of the action and to serve 60 days in jail. The jail sentence was suspended, and the defendant was placed on probation for 60 days.

3844. Misbranding of Seconal Sodium capsules and dextro-amphetamine sulfate tablets. U. S. v. Orville L. Wright (Wright Pharmacy). Plea of not guilty. Tried to the court and jury. Verdict of guilty. Fine of $500; sentence of six months in jail suspended and defendant placed on probation for five years. (F. D. C. No. 31296. Sample Nos. 21191–L, 21192–L, 21194–L to 21196–L, incl.)

INFORMATION FILED: January 24, 1952, Southern District of Texas, against Orville L. Wright, trading as the Wright Pharmacy, Houston, Tex.

ALLEGED VIOLATION: On or about June 19 and 30 and July 3 and 9, 1951, while a number of *Seconal Sodium capsules* and *dextro-amphetamine sulfate tablets* were being held for sale at the Wright Pharmacy after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *Seconal Sodium capsules* and 1 lot of the repackaged *dextro-amphetamine sulfate tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before the court and jury on October 20, 1952. The trial was concluded on October 21, 1952, with the return by the jury of a verdict of guilty. On October 29, 1952, the court imposed a fine of $500, a sentence of six months in jail, which was suspended, and placed the defendant on probation for five years.

3845. Misbranding of amphetamine sulfate tablets and capsules of Seconal Sodium and Amytal Sodium. U. S. v. Neal A. Brady (Brady Drugs). Plea of nolo contendere. Fine of $600, plus costs. (F. D. C. No. 32726. Sample Nos. 18811–L, 18813–L, 18816–L, 18819–L.)

INFORMATION FILED: September 16, 1952, Southern District of Iowa, against Neal A. Brady, trading as Brady Drugs, Des Moines, Iowa.

ALLEGED VIOLATION: On or about October 28 and November 4 and 12, 1951, while a number of *amphetamine sulfate tablets* and capsules of *Seconal Sodium* and *Amytal Sodium* were being held for sale at Brady Drugs after shipment in interstate commerce, the defendant caused various quantities of the capsules and tablets to be repackaged and dispensed without a physician's prescription, which acts resulted in the capsules and tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs, with the exception of one lot of the capsules, failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged capsules contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportions of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the label of the repackaged tablets failed to bear the common or usual name of each active ingredient of the drug.

DISPOSITION: January 27, 1953. The defendant having entered a plea of nolo contendere, the court imposed a fine of $600, plus costs.

3846. Misbranding of Benzedrine Sulfate tablets, Seconal Sodium capsules, and Savatan capsules. U. S. v. Warren Pizinger and Henry Fiegenbaum. Pleas of nolo contendere. Fine of $1,000, plus costs, against Defendant Pizinger and $250 against Defendant Fiegenbaum; each defendant also placed on probation for 3 years. (F. D. C. No. 31253. Sample Nos. 55968–K, 55969–K, 70189–K.)

INFORMATION FILED: November 28, 1951, District of Nebraska, against Warren Pizinger, manager of the City Drug Store, 4502 South 24th St., Omaha, Nebr., and Henry Fiegenbaum, a pharmacist in the store.

ALLEGED VIOLATION: On or about July 19, 24, and 25, 1950, while quantities of *Benzedrine Sulfate tablets*, *Seconal Sodium capsules*, and *Savatan capsules* were being held for sale at the above-mentioned drug store after shipment in interstate commerce, Warren Pizinger caused one box of *Savatan capsules* to be sold and disposed of in the original box in which such capsules had been shipped in interstate commerce, without the prescription of a physician; and Henry Fiegenbaum repacked and dispensed a number of *Benzedrine Sulfate tablets* and Warren Pizinger repacked and dispensed a number of *Seconal Sodium capsules* without prescriptions of physicians, which acts of the defendants resulted in the drugs being misbranded.

NATURE OF CHARGE: *Savatan capsules.* Misbranding, Section 502 (f) (1), the labeling of the capsules bore no directions for use. (The box in which the capsules were shipped in interstate commerce bore no directions for use since it was exempt from such requirements by the statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of Warren Pizinger in dispensing the drug without a physician's prescription, however, caused the exemption to expire.)

Benzedrine Sulfate tablets and *Seconal Sodium capsules.* Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use. Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: A motion for a bill of particulars was filed on behalf of the defendants and was allowed by the court with respect to the request that the Government furnish particulars as to the manner in which the defendants had caused the drugs to be repacked and dispensed. In accordance with such ruling, the Government filed a bill of particulars on April 23, 1952. Thereafter, a motion for dismissal of the information was filed on behalf of the defendants, and was overruled by the court on May 29, 1952. The defendants subsequently entered pleas of nolo contendere, and on October 30, 1952, the court imposed a fine of $1,000, plus costs, against Defendant Pizinger and $250 against Defendant Fiegenbaum and placed each defendant on probation for 3 years.

3847. Alleged misbranding of Seconal Sodium capsules and pentobarbital sodium capsules. U. S. v. Wells B. Kilgore (Kilgore's Pharmacy), and Weldon R. Rehburg. Pleas of not guilty. Motion granted for dismissal of the information and defendants discharged as not guilty. (F. D. C. No. 31274. Sample Nos. 93082-K, 93087-K, 93091-K, 93097-K, 93201-K, 93208-K, 93213-K, 93217-K, 93225-K, 93226-K, 93228-K.)

INFORMATION FILED: January 8, 1952, Southern District of Florida, against Wells B. Kilgore, trading as Kilgore's Pharmacy, St. Petersburg, Fla., and Weldon R. Rehburg, a pharmacist employed by Mr. Kilgore.

ALLEGED VIOLATION: Between the approximate dates of October 24 and December 18, 1950, while a number of *Seconal Sodium capsules* and *pentobarbital sodium capsules* were being held for sale at Kilgore's Pharmacy after shipment in interstate commerce, various quantities of the drugs were

repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

Wells B. Kilgore was charged with causing the acts of repacking and dispensing in each of the eight counts of the information, and Weldon R. Rehburg was joined as a defendant in three counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drugs contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the name, and quantity or proportion of each derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

DISPOSITION: Pleas of not guilty were entered on behalf of the defendants on February 12, 1952. A motion for dismissal of the information was filed on behalf of the defendants on or about February 18, 1952. On August 1, 1952, the court entered an order granting the motion to dismiss and discharging the defendants as not guilty, based upon the same reasons as set forth in the order of dismissal which was entered in the case reported in the following notice of judgment, No. 3848.

3848. Alleged misbranding of Seconal Sodium capsules and pentobarbital sodium capsules. U. S. v. Forest C. Pomroy (Pomroy's Drug Store). Plea of guilty. Motion for dismissal of the information granted and defendants discharged as not guilty. (F. D. C. No. 31271. Sample Nos. 93084–K, 93089–K, 93093–K, 93099–K, 93203–K, 93210–K, 93212–K, 93221–K, 93222–K, 93238–K.)

INFORMATION FILED: January 8, 1952, Southern District of Florida, against Webb's City, Inc., St. Petersburg, Fla., and Charles L. Fox, manager of the prescription department of the corporation.

ALLEGED VIOLATION: Between the approximate dates of October 24 and December 19, 1950, while quantities of *Seconal Sodium capsules* and *pentobarbital sodium capsules* were being held for sale at Webb's City, Inc., after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drugs contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the name, and quantity or proportion of each derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

DISPOSITION: Pleas of not guilty were entered on behalf of the defendants on or about February 12, 1952, and a motion for dismissal of the information was filed on behalf of the defendants on or about February 18, 1952. On August 1, 1952, the court entered the following order granting the motion:

BARKER, *District Judge:* "This cause came on to be heard upon the Motion to Dismiss filed herein by the defendants, and the Court having heard the argument of counsel, and counsel for the defendants and for the United States of America having stipulated before the Court that the facts in support of the offense sought to be charged in each count consist of refilling prescriptions for certain drugs by the defendants when there was a physician's prescription on file with the defendants;

"And the Court being advised that refilling of such prescriptions was a practice of long standing with druggists, and that for many years the administrator of the Federal Food, Drugs and Cosmetics Act did not seek to restrict refills of prescriptions and after it sought to do so, the Congress adopted a clarifying and definitive amendment, and the Court being of the opinion that facts supporting the offense sought to be charged, viz refilling prescriptions, do not constitute a criminal offense adequately and definitely spelled out in the statute and regulations as is required for a criminal prosecution;

"It is thereupon ordered that the said motion is hereby granted and the information is hereby dismissed, and the defendants are hereby released from process and discharged as not guilty.

"Done and ordered this 1st day of August A. D., 1952."

3849. Alleged misbranding of Seconal Sodium capsules and pentobarbital sodium capsules. U. S. v. Forest C. Pomeroy (Pomeroy's Drug Store). Plea of not guilty. Motion granted for dismissal of the information and defendant discharged as not guilty. (F. D. C. No. 31273. Sample Nos. 93083–K, 93088–K, 93092–K, 93098–K, 93202–K, 93209–K, 93214–K, 93230–K, 93233–K, 93236–K.)

INFORMATION FILED: January 8, 1952, Southern District of Florida, against Forest C. Pomeroy, trading as Pomeroy's Drug Store, St. Petersburg, Fla.

ALLEGED VIOLATION: Between the approximate dates of October 24 and December 18, 1950, while a number of *Seconal Sodium capsules* and *pentobarbital sodium capsules*, were being held for sale at Pomeroy's Drug Store after shipment in interstate commerce, the defendant caused various quantities of such drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drugs contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the name, and quantity or proportion of each derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

DISPOSITION: On February 12, 1952, a plea of not guilty was entered on behalf of the defendant, and on or about February 18, 1952, a motion for dismissal of the information was filed on behalf of the defendant. On August 1, 1952, the court entered an order granting the motion to dismiss and discharging the defendant as not guilty, based upon the same reasons as set forth in the

order of dismissal which was entered in the case reported in the preceding notice of judgment, No. 3848.

3850. Misbranding of pentobarbital sodium capsules and Seconal Sodium capsules. U. S. v. Harry W. Anderson, Willie P. Norvell, and John P. Asbill. Pleas of nolo contendere. Each defendant placed on probation for 2 years and fined $50. (F. D. C. No. 32696. Sample Nos. 1325–L, 1331–L, 1333–L, 1335–L, 1336–L, 1423–L, 1514–L, 1517–L, 1841–L.)

INFORMATION FILED: June 20, 1952, Southern District of Georgia, against Harry W. Anderson and Willie P. Norvell, pharmacists and partners in the partnership of the Lake View Pharmacy, Augusta, Ga., and John P. Asbill, a pharmacist employed by the partnership.

ALLEGED VIOLATION: On or about May 7, 15, 16, 21, 28, and 30, and June 4, 1951, while a number of *pentobarbital sodium capsules* and *Seconal Sodium capsules* were being held for sale at the Lake View Pharmacy after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

Harry W. Anderson was charged with causing the dispensing of the drugs involved in three counts of the information, Willie P. Norvell with causing the dispensing of the drugs involved in four counts of the information, and John P. Asbill with causing the dispensing of the drug involved in the remaining two counts of the information.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the drugs contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and when repackaged their labels failed to bear the name, and quantity or proportion of each derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

DISPOSITION: December 1, 1952. Pleas of nolo contendere having been entered, the court placed each defendant on probation for 2 years and fined each $50.

3851. Misbranding of pentobarbital sodium capsules and sulfathiazole tablets. U. S. v. Willard H. Quigley (Edward Drug Store), Frank Coll, and Charles Kemper. Pleas of nolo contendere. Fine of $1,000, plus costs, against Defendant Quigley; $500 against Defendant Coll; and $500 against Defendant Kemper. (F. D. C. No. 30591. Sample Nos. 70184–K, 70193–K.)

INFORMATION FILED: July 31, 1951, District of Nebraska, against Willard H. Quigley, trading as the Edward Drug Store, Omaha, Nebr., and against Frank Coll, an employee, and Charles Kemper, a pharmacist, at the store. An amended information was filed on January 17, 1952.

ALLEGED VIOLATION: On or about July 14 and 20, 1950, while a number of *pentobarbital sodium capsules* and *sulfathiazole tablets* were being held for sale at the Edward Drug Store after shipment in interstate commerce, a quantity of the capsules and tablets were repacked and disposed of without a prescription issued by a physician in his professional practice, which acts resulted in the repackaged drugs being misbranded.

Defendants Quigley and Kemper were charged with causing the repacking and disposal of the *pentobarbital sodium capsules*, and Defendants Quigley and Coll were charged with causing the repacking and disposal of the *sulfathiazole tablets*.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *pentobarbital sodium capsules* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *sulfathiazole tablets* failed to bear a label containing the common or usual name of the drug; and Section 502 (f) (2), the repackaged *sulfathiazole tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: Motions for a bill of particulars and for dismissal of the information were filed on behalf of the defendants and subsequently were overruled by the court. Thereafter, the defendants entered pleas of nolo contendere, and on October 30, 1952, the court imposed a fine of $1,000, plus costs, against Defendant Quigley, a fine of $500 against Defendant Coll, and a fine of $500 against Defendant Kemper.

3852. Misbranding of Combisul tablets, Pentresamide tablets, and Seconal Sodium capsules. U. S. v. Riverhead Drug Co., Inc., and Edward A. Schwartz. Pleas of guilty. Fine of $250 against corporation and $750 against Defendant Schwartz. Individual defendant placed on probation for 1 year. (F. D. C. No. 31302. Sample Nos. 91993–K, 24571–L to 24573–L, incl., 24576–L.)

INFORMATION FILED: September 10, 1952, Eastern District of New York, against Riverhead Drug Co., Inc., Riverhead, L. I., N. Y., and Edward A. Schwartz, president and treasurer of the corporation.

ALLEGED VIOLATION: On or about November 14, 1950, and January 16, 21, and 26, 1951, while a number of *Combisul tablets*, *Pentresamide tablets*, and *Seconal Sodium capsules* were being held for sale at the Riverhead Drug Co., Inc., after shipment in interstate commerce, Riverhead Drug Co., Inc., and Edward A. Schwartz caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and designated by regulations as, habit forming; and the capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *Combisul tablets* and *Pentresamide tablets* failed to bear labels containing the common or usual name of each active ingredient of the tablets; and, Section 502 (f) (2), the repackaged *Combisul tablets* and *Pentresamide tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: December 12, 1952. Pleas of guilty having been entered, the court imposed a fine of $250 against the corporation and $750 against Defendant Schwartz and placed the individual on probation for 1 year.

3853. Misbranding of Seconal Sodium capsules, thyroid tablets, and methyltestosterone tablets. U. S. v. Manuel M. Lazear (Northside Drug). Plea of nolo contendere. Defendant fined $200, plus costs, and placed on probation for 3 years. (F. D. C. No. 31304. Sample Nos. 6883–L, 6891–L, 6893–L, 6895–L, 7101–L, 7114–L, 7115–L, 7122–L.)

INFORMATION FILED: March 25, 1952, Western District of Pennsylvania, against Manuel M. Lazear, trading as Northside Drug, Pittsburgh, Pa.

ALLEGED VIOLATION: On or about March 6, 15, and 27, and April 6, 9, and 11, 1951, while a number of *Seconal Sodium capsules*, *thyroid tablets*, and *methyltestosterone tablets* were being held for sale at Northside Drug after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the label of the repackaged *thyroid tablets* failed to bear the common or usual name of the tablets.

DISPOSITION: January 14, 1953. A plea of nolo contendere having been entered, the court imposed a fine of $50 on each of counts 1, 2, 3, and 4 of the information, or a total fine of $200, suspended the imposition of sentence on the remaining 4 counts and placed the defendant on probation for 3 years.

3854. Misbranding of Dexedrine Sulfate tablets, sulfadiazine tablets, apiol and ergot capsules, and Seconal Sodium capsules. U. S. v. Woodard Roberts Mitchell. Plea of not guilty. Tried to the court. Verdict of guilty. Fine, $175. (F. D. C. No. 30029. Sample Nos. 70840-K, 70841-K, 70843-K, 70844-K, 70846-K, 70849-K, 70850-K.)

INFORMATION FILED: February 15, 1951, Western District of Oklahoma, against Woodard Roberts Mitchell, pharmacist and manager of K & W Drug, Oklahoma City, Okla.

ALLEGED VIOLATION: On or about April 22, 23, 24, 26, and 28, and May 1, 1950, while a number of *Dexedrine Sulfate tablets, sulfadiazine tablets, apiol and ergot capsules,* and *Seconal Sodium capsules* were being held for sale at K & W Drug after shipment in interstate commerce, Woodard Roberts Mitchell caused quantities of such drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged *Dexedrine Sulfate tablets, sulfadiazine tablets,* and *apiol and ergot capsules* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of such capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *Dexedrine Sulfate tablets* and *sulfadiazine tablets* failed to bear labels containing the common or usual name of the drugs; Section 502 (e) (2), the repackaged *apiol and ergot capsules* failed to bear a label containing the common or usual name of each active ingredient of the drug; Section 502 (f) (1), the repackaged *Dexedrine Sulfate tablets, apiol and ergot capsules,* and *Seconal Sodium capsules* failed to bear labeling containing adequate directions for use; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: A motion to quash the information on the ground that the information was duplicitous and a motion for a bill of particulars were filed by the defendant on March 23, 1951. On September 27, 1951, the court overruled these motions, and the case came on for trial on January 23, 1952, upon the defendant's plea of not guilty. The trial was concluded on the same day, with the return by the court of a verdict of guilty and the imposition of a fine of $175.

3855. Misbranding of amphetamine citrate tablets, pentobarbital sodium capsules, and apiol and ergot. U. S. v. Charles Pizinger and Donald White. Pleas of nolo contendere. Defendant Pizinger fined $1,500, plus costs, and placed on probation for 3 years; Defendant White fined $500 and placed also on probation for 3 years. (F. D. C. No. 31252. Sample Nos. 70181–K, 70182–K, 70188–K, 89805–K.)

INFORMATION FILED: November 28, 1951, District of Nebraska, against Charles Pizinger, pharmacist and manager of the City Drug Store at 2823 Leavenworth Street, Omaha, Nebr., and Donald White, an employee of the store.

ALLEGED VIOLATION: On or about July 14, 17, and 25, 1950, while quantities of *amphetamine citrate tablets*, *pentobarbital sodium capsules*, and *apiol and ergot capsules* were being held for sale at the above-mentioned City Drug Store after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

Defendant Pizinger was charged with causing the repacking and dispensing of each of the drugs involved in three different counts of the information, and Defendant White was charged with causing such acts to be done with respect to a quantity of *pentobarbital sodium capsules* as alleged in an additional count in the information.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *pentobarbital sodium capsules* and *apiol and ergot capsules* failed to bear labels of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *amphetamine citrate tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the repackaged *apiol and ergot capsules* were fabricated from two or more ingredients, and they failed to bear a label containing the common or usual name of each active ingredient; and, Section 502 (f) (2), the repackaged *apiol and ergot capsules* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: A motion for a bill of particulars was filed by the defendants on January 3, 1952, and was overruled by the court, with the exception of that part in which the Government was requested to show how the defendants "caused" the various drugs to be repacked and dispensed. In accordance with such ruling, the Government filed a bill of particulars on April 23, 1952. Thereafter a motion for dismissal of the information was filed on behalf of the defendants, and after consideration of the arguments of counsel, it was overruled by the court on May 29, 1952. Pleas of nolo contendere subsequently

were entered on behalf of the defendants, and on October 30, 1952, Defendant Pizinger was fined $1,500, plus costs, and Defendant White was fined $500. Each defendant also was placed on probation for 3 years.

3856. Misbranding of apiol and ergot capsules, dextro-amphetamine sulfate tablets, methamphetamine hydrochloride tablets, capsules of pentobarbital sodium and aspirin, and methyltestosterone tablets. U. S. v. Clarence L. Fedler (Fedler's Pharmacy), and Ollie Gilmer. Pleas of nolo contendere. Fine of $300 against Defendant Fedler and $50 against Defendant Gilmer. (F. D. C. No. 32732. Sample Nos. 16082-L, 16083-L, 16085-L, 16087-L, 16088-L, 16090-L, 16092-L.)

INFORMATION FILED: October 16, 1952, Eastern District of Oklahoma, against Clarence L. Fedler, trading as Fedler's Pharmacy, Ardmore, Okla., and Ollie Gilmer, a pharmacist.

ALLEGED VIOLATION: On or about October 12 and 15, 1951, while quantities of *apiol and ergot capsules*, *dextro-amphetamine sulfate tablets*, *methamphetamine hydrochloride tablets*, capsules of *pentobarbital sodium and aspirin*, and *methyltestosterone tablets* were being held for sale at Fedler's Pharmacy after shipment in interstate commerce, Defendant Fedler caused 1 box of *apiol and ergot capsules* to be dispensed in the original box in which the capsules had been shipped in interstate commerce, without the prescription of a physician; and Defendant Fedler caused various quantities of the other drugs, and Defendant Gilmer caused a number of *dextro-amphetamine sulfate tablets*, to be repacked and dispensed without prescriptions, which acts resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the *apiol and ergot capsules* failed to bear adequate directions for use. (The box in which the capsules had been shipped in interstate commerce bore no directions for use since it was exempted from such requirement by a statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of Defendant Fedler in dispensing the drug without a physician's prescription caused the exemption to expire.)

Further misbranding, Sections 502 (b) (1) and (2), all of the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged capsules of *pentobarbital sodium and aspirin* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), a portion of the repackaged *dextro-amphetamine sulfate tablets* failed to bear a label containing the common or usual name of the active ingredient of the tablets; Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use; and, Section 502 (f) (2), the repackaged *methamphetamine hydrochloride tablets* and a portion of the *dextro-amphetamine sulfate tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: November 14, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $300 against Defendant Fedler and a fine of $50 against Defendant Gilmer.

3857. Misbranding of methyltestosterone tablets, dextro-amphetamine sulfate tablets, thyroid tablets, tablets of phenobarbital and mannitol hexanitrate, and capsules of pentobarbital sodium and aspirin. U. S. v. A-B Drug Co., a partnership, and Calvin Bigley and John R. Burns. Pleas of nolo contendere. Partnership fined $240; Calvin Bigley, $15; and John R. Burns, $45. (F. D. C. No. 32729. Sample Nos. 15419–L to 15421–L, incl., 15423–L, 15425–L, 15426–L, 15428–L, 15429–L.)

INFORMATION FILED: September 18, 1952, Western District of Oklahoma, against the A-B Drug Co., Lawton, Okla., a partnership, and Calvin Bigley, pharmacist, and John R. Burns, an employee of the partnership.

INTERSTATE SHIPMENT: Prior to the dates of the sales reported below, various quantities of *methyltestosterone tablets, dextro-amphetamine sulfate tablets, thyroid tablets,* tablets of *phenobarbital and mannitol hexanitrate,* and capsules of *pentobarbital sodium and aspirin* were shipped in interstate commerce into the State of Oklahoma.

ALLEGED VIOLATION: On or about October 11, 13, 15, and 22, 1951, while the drugs were being held for sale after shipment in interstate commerce, 1 bottle of *thyroid tablets* was sold and disposed of to a purchaser in the original bottle in which the tablets had been shipped in interstate commerce, without the prescription of a physician; and various quantities of the other drugs were repacked and sold without prescriptions, which acts resulted in the drugs being misbranded.

The A-B Drug Co. was charged with causing the violations involved in all counts, and, in addition, Calvin Bigley was joined in 1 count and John R. Burns was joined in 3 counts and charged with causing the violations involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the *thyroid tablets* failed to bear adequate directions for use. (The bottle in which the tablets had been shipped in interstate commerce bore no directions for use since it was exempted from such requirement by a statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendants in dispensing the drug without a physician's prescription caused the exemption to expire.)

Further misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged tablets of *phenobarbital and mannitol hexanitrate* and capsules of *pentobarbital sodium and aspirin* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of the drugs failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: November 20, 1952. Pleas of nolo contendere having been entered by the defendants, the court fined the A–B Drug Co. $240, Calvin Bigley $15, and John R. Burns $45.

3858. Misbranding of tablets of mannitol hexanitrate and phenobarbital, diethylstilbestrol tablets, phenobarbital tablets, methyltestosterone tablets, and dextro-amphetamine sulfate tablets. U. S. v. Orville L. Moffett and Gerald F. Tharp. Pleas of guilty. Fine of $150, plus costs, against Defendant Tharp and $50 against Defendant Moffett. (F. D. C. No. 33719. Sample Nos. 30955–L, 30965–L, 32497–L, 32527–L, 32530–L, 34293–L, 34294–L, 34297–L.)

INFORMATION FILED: October 10, 1952, Western District of Missouri, against Orville L. Moffett and Gerald F. Tharp, pharmacists for the Nu-Way Stores, a partnership, Joplin, Mo.

ALLEGED VIOLATION: On or about May 14 and 25, July 31, and October 1 and 31, 1951, while quantities of tablets of *mannitol hexanitrate and phenobarbital*, *diethylstilbestrol tablets*, *phenobarbital tablets*, *methyltestosterone tablets*, and *dextro-amphetamine sulfate tablets* were being held for sale at the Nu-Way Stores after shipment in interstate commerce, Orville L. Moffett caused a number of tablets of *mannitol hexanitrate and phenobarbital*, and Gerald F. Tharp caused a number of tablets of the other drugs, to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* and the tablets of *mannitol hexanitrate and phenobarbital* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *methyltestosterone tablets* failed to bear a label containing the common or usual name of the drug; and, Section 502 (e) (2), the repackaged *dextro-amphetamine sulfate tablets* and a portion of the repackaged tablets of *mannitol hexanitrate and phenobarbital* failed to bear labels containing the common or usual name of each active ingredient of the drugs.

DISPOSITION: December 1, 1952. Pleas of guilty having been entered, the court imposed a fine of $150, plus costs, against Defendant Tharp and a fine of $50 against Defendant Moffett.

3859. Misbranding of dextro-amphetamine sulfate tablets, Seconal Sodium capsules, methamphetamine hydrochloride tablets, and methyltestosterone tablets. U. S. v. Mose Drug, Inc., and Roy I. Preston and Vinton B. Clark. Pleas of nolo contendere. Fine of $200 against corporation, $75 against Defendant Preston, and $45 against Defendant Clark. (F. D. C. No. 32730. Sample Nos. 15475–L to 15477–L, incl., 15481–L, 15482–L, 15484–L, 15488–L, 15489–L.)

INFORMATION FILED: September 18, 1952, Western District of Oklahoma, against Mose Drug, Inc., Lawton, Okla., and Roy I. Preston, a pharmacist, and Vinton B. Clark, an employee.

ALLEGED VIOLATION: On or about September 9 and 29 and October 11, 13, 15, and 22, 1951, while quantities of *dextro-amphetamine sulfate tablets*, *Seconal Sodium capsules*, *methamphetamine hydrochloride tablets*, and *methyltestosterone tablets* were being held for sale at Mose Drug, Inc., after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

Mose Drug, Inc., was charged with causing the acts of repacking and dispensing of the drugs involved in each of the 8 counts of the information, and, in addition, Defendant Preston, in 5 of the counts, and Defendant Clark, in 3 of the counts, were charged with causing such acts to be done in connection with the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), portions of the repackaged *dextro-amphetamine sulfate tablets* and *methyltestosterone tablets* and all of the repackaged *methamphetamine hydrochloride tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *dextro-amphetamine sulfate tablets* and *methamphetamine hydrochloride tablets* and a portion of the *methyltestosterone tablets* failed to bear labels containing the common or usual name of the active ingredients of the drugs; and, Section 502 (f) (2), the repackaged *methamphetamine hydrochloride tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: November 20, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $200 against the corporation, $75 against Defendant Preston, and $45 against Defendant Clark.

3860. Misbranding of diethylstilbestrol tablets and dextro-amphetamine sulfate tablets. U. S. v. Grover C. Gearien (Gearien's Prescription Store). Plea of guilty. Fine of $500, plus costs. (F. D. C. No. 33728. Sample Nos. 32704–L, 34339–L, 34350–L, 34352–L, 34454–L.)

INFORMATION FILED: November 20, 1952, Southern District of Illinois, against Grover C. Gearien, trading as Gearien's Prescription Store, Chillicothe, Ill.

ALLEGED VIOLATION: On or about February 20, 25, 26, and 28, and March 3, 1952, while a number of *diethylstilbestrol tablets* and *dextro-amphetamine sulfate tablets* were being held for sale at Gearien's Prescription Store after shipment in interstate commerce, the defendant caused quantities of such tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use; and, Section 502 (f) (2), the labeling of the repackaged *diethylstilbestrol tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: December 3, 1952. A plea of guilty having been entered, the court imposed a fine of $500, plus costs.

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[2] (3841) Prosecution contested. Contains charge to the jury.
[3] (3848) Prosecution contested. Contains order of the court.
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[1] (3844, 3847, 3849, 3854) Prosecution contested.
[2] (3841) Prosecution contested. Contains charge to the jury.

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[1] (3844, 3847, 3849, 3854) Prosecution contested.
[3] (3848) Prosecution contested. Contains order of the court.
[4] (3842) Prosecution contested. Contains opinion of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1953

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3861–3880

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the U. S. Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *May 14, 1953.*

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250655—53——1

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUG FOR VETERINARY USE

3861. Adulteration and misbranding of Wonder mange capsules. U. S. v. John M. Adams. Plea of guilty. Defendant placed on probation for 2 years. (F. D. C. No. 32708. Sample Nos. 21028–L, 21212–L, 29044–L.)

INFORMATION FILED: June 6, 1952, Northern District of Alabama, against John M. Adams, manager of the J. Q. Adams Drug Co., Ashland, Ala.

ALLEGED SHIPMENT: On or about March 15 and April 25, 1951, from the State of Alabama into the States of Texas and Oregon.

LABEL, IN PART: "Wonder Mange Capsules (Canine) Caution:—Not for Human Use Each capsule contains 10 grains Sodium 2 Arsenious Acid."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since it purported and was represented to contain 10 grains of a sodium compound of arsenious acid in each capsule, whereas the article did not contain 10 grains of a sodium compound of arsenious acid in each capsule but contained in excess of 10 grains of arsenic trioxide in each capsule.

Misbranding, Section 502 (a), the label statement "Each capsule contains 10 grains Sodium 2 Arsenious Acid" was false and misleading since the article contained in excess of 10 grains of arsenic trioxide in each capsule, and the label statements "Wonder Mange Capsules (Canine)" and "Uses: These capsules may be used in the treatment of All Types of Mange On Dogs" were false and misleading since the statements represented and suggested that the article would be effective in the treatment of all types of mange on dogs, whereas it would not be effective in the treatment of any type of mange on dogs.

Further misbranding, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, namely, arsenic trioxide; and, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, namely, "Dogs over 10 pounds body weight should receive one capsule every 3 days until symptoms disappear."

DISPOSITION: October 24, 1952. A plea of guilty having been entered, the court placed the defendant on probation for 2 years.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

3862. Misbranding of Tuinal capsules, Secobarbital Sodium capsules, racemic amphetamine sulfate tablets, pentobarbital sodium capsules, and methyltestosterone linguets. U. S. v. Highland Pharmacies, Inc., and Alec Mendelsohn. Plea of nolo contendere for corporation and plea of guilty for individual. Corporation fined $750; sentence of 90 days in prison imposed against individual. (F. D. C. No. 33714. Sample Nos. 15851–L to 15864–L, incl.)

INFORMATION FILED: October 6, 1952, Western District of Missouri, against Highland Pharmacies, Inc., Kansas City, Mo., and Alec Mendelsohn, manager of the corporation's Store No. 2, at Kansas City, Mo.

NATURE OF CHARGE: On or about July 14, 17, 18, 21, and 22, 1952, while quantities of *Tuinal capsules, Secobarbital Sodium capsules, racemic amphetamine sulfate tablets, pentobarbital sodium capsules,* and *methyltestosterone linguets* were being held for sale at Highland Pharmacies, Inc., Store No. 2, after shipment in interstate commerce, the defendants caused various quantities of the drugs to be dispensed without prescriptions from practitioners licensed by law to administer such drugs. This dispensing was contrary to Section 503 (b) (1) and resulted in the drugs so dispensed being misbranded while held for sale.

DISPOSITION: November 14, 1952. A plea of nolo contendere having been entered on behalf of the corporation and a plea of guilty on behalf of the individual defendant, the court imposed a fine of $750 against the corporation and sentenced the individual to 90 days in prison.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3863. Misbranding of phenobarbital tablets, dextro-amphetamine sulfate tablets, sulfadiazine tablets, and diethylstilbestrol tablets. U. S. v. John E. Stephens (John E. Stephens Drugs), and Andrew J. Collinsworth. Pleas of nolo contendere. John E. Stephens fined $2,000 and Andrew J. Collinsworth $500. (F. D. C. No. 31264. Sample Nos. 31371–L, 31373–L, 31915–L, 31916–L, 31923–L, 31924–L, 31926–L, 31927–L.)

INFORMATION FILED: December 6, 1951, Western District of Tennessee, against John E. Stephens, trading as John E. Stephens Drugs, at Memphis, Tenn., and Andrew J. Collinsworth, pharmacist.

INTERSTATE SHIPMENT: From the States of Pennsylvania and Indiana into the State of Tennessee, of quantities of *phenobarbital tablets, dextro-amphetamine sulfate tablets, sulfadiazine tablets,* and *diethylstilbestrol tablets.*

ALLEGED VIOLATION: On or about February 20 and 23, April 28 and 29, and May 6, 10, and 11, 1951, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

John E. Stephens, as owner, was made a defendant in all counts; and, in addition, Andrew J. Collinsworth, the pharmacist, was joined as a defendant in three of the counts involving sales made by him.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged drug failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* bore no warning against use in those pathological con-

*See also No. 3878 (veterinary preparation).

ditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: December 14, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of $2,000 against John E. Stephens and $500 against Andrew J. Collinsworth.

3864. Misbranding of inositol hexanitrate and phenobarbital tablets, thyroid tablets, dextro-amphetamine sulfate tablets, and sulfadiazine tablets. U. S. v. Joseph K. Carlisle (Carlisle Drug Store). Plea of guilty. Fine of $500, plus costs. (F. D. C. No. 33729. Sample Nos. 34340–L, 34347–L, 34348–L, 34354–L, 34355–L, 34453–L.)

INFORMATION FILED: November 20, 1952, Southern District of Illinois, against Joseph K. Carlisle, trading as Carlisle Drug Store, Chillicothe, Ill.

ALLEGED VIOLATION: On or about February 20, 25, and 28, and March 3, 1952, while quantities of *inositol hexanitrate and phenobarbital tablets, thyroid tablets, dextro-amphetamine sulfate tablets,* and *sulfadiazine tablets* were being held for sale at the Carlisle Drug Store after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *inositol hexanitrate and phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of such repackaged drug failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the repackaged *inositol hexanitrate and phenobarbital tablets* and *dextro-amphetamine sulfate tablets* were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: December 3, 1952. A plea of guilty having been entered, the court imposed a fine of $500, plus costs.

3865. Misbranding of Combisul–DM tablets, dextro-amphetamine sulfate tablets, and pentobarbital sodium capsules. U. S. v. Irving L. Rutkoff (Fayetteville Pharmacy). Plea of guilty. Fine, $104. (F. D. C. No. 31298. Sample Nos. 74167–K, 74169–K, 74171–K, 74174–K, 74176–K.)

INFORMATION FILED: May 15, 1952, Northern District of New York, against Irving L. Rutkoff, trading as the Fayetteville Pharmacy, Fayetteville, N. Y.

ALLEGED VIOLATION: On or about October 30 and November 1, 8, and 27, 1950, while quantities of *Combisul–DM tablets, dextro-amphetamine sulfate tablets,*

and *pentobarbital sodium capsules* were being held for sale at the Fayetteville Pharmacy after shipment in interstate commerce, the defendant caused 1 bottle of the *Combisul-DM tablets* and 1 bottle of the *dextro-amphetamine sulfate tablets* to be dispensed without the prescription of a physician to purchasers in the original bottles in which the tablets had been shipped in interstate commerce; and, in addition, the defendant caused various quantities of the *pentobarbital sodium capsules* and the *Combisul-DM tablets* to be repacked and dispensed without prescriptions, which acts of the defendant resulted in the dispensed drugs being misbranded.

NATURE OF CHARGE: *Combisul-DM tablets* and *dextro-amphetamine sulfate tablets* (dispensed in original bottles). Misbranding, Section 502 (f) (1), the labeling of the drugs failed to bear adequate directions for use. (The bottles in which the tablets were shipped in interstate commerce bore no directions for use since they were exempted from such requirement by the statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendant in dispensing such drugs without a physician's prescription caused the exemption to expire.)

Pentobarbital sodium capsules and *Combisul-DM tablets* (repackaged portions). Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *Combisul-DM tablets* were not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients, and their label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the repackaged *pentobarbital sodium capsules* and *Combisul-DM tablets* failed to bear adequate directions for use; and, Section 502 (f) (2), the repackaged *Combisul-DM tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 15, 1952. A plea of guilty having been entered, the court imposed a fine of $104.

3866. Misbranding of Nembutal capsules and Benzedrine Sulfate tablets. U. S. v. Lew Wallace (Wallace Rexall Drugs), John W. Gordon, Jr., and George M. Smith. Pleas of nolo contendere. Fine of $50 against each defendant. (F. D. C. No. 28136. Sample Nos. 53420-K, 53885-K, 53890-K, 53898-K, 53900-K, 53913-K, 53968-K, 53969-K, 54126-K.)

INFORMATION FILED: September 14, 1950, Southern District of Mississippi, against Lew Wallace, a partner in the firm of Wallace Rexall Drugs, Laurel, Miss., and against John W. Gordon, Jr., and George M. Smith, pharmacists in the business.

ALLEGED VIOLATION: Between the approximate dates of June 1 and August 4, 1949, while a number of *Nembutal capsules* and *Benzedrine Sulfate tablets* were being held for sale at Wallace Rexall Drugs after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

Lew Wallace was charged with making 1 sale of *Benzedrine Sulfate tablets;* George M. Smith was charged with 2 sales of *Nembutal capsules* and 1 sale of *Benzedrine Sulfate tablets;* and John W. Gordon, Jr., was charged with 4 sales of *Nembutal capsules* and 1 sale of *Benzedrine Sulfate tablets.*

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *Benzedrine Sulfate tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *Nembutal capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: On October 17, 1951, upon the basis of pleas of nolo contendere entered by John W. Gordon, Jr., and George M. Smith, the court imposed a fine of $50 against each defendant.

On October 31, 1952, following a plea of nolo contendere by Lew Wallace, the court imposed a fine of $50 against this defendant.

3867. Adulteration and misbranding of dextro-amphetamine sulfate tablets. U. S. v. 11 Bottles * * *. (F. D. C. No. 31382. Sample No. 11174–L.)

LIBEL FILED: July 23, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 1 and 15, 1951, by the International Pharmaceutical Laboratories, from Great Neck, N. Y.

PRODUCT: 11 unlabeled bottles of *dextro-amphetamine sulfate tablets* at Cleveland, Ohio.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance, namely 4.2-milligram amphetamine tablets, had been substituted for 5-milligram *dextro-amphetamine sulfate tablets.*

Misbranding, Section 502 (i) (2), the article was an imitation of another drug; Section 502 (i) (3), it was offered for sale under the name of another drug; Sections 502 (b) (1) and (2), it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), its label failed to bear the common or usual name of the drug, amphetamine sulfate tablets; Section 502 (f) (1), its labeling failed to bear adequate directions for use; and, Section 502 (f) (2), its labeling failed to bear such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: The Lipton Drug & Sales Co. filed an answer to the libel, to which answer the Government, on October 5, 1951, filed a motion for a summary judgment. On November 20, 1951, the court granted the Government's motion for a summary judgment based on the admissions in the claimant's answer that the drug was transported in interstate commerce without being labeled; and the court also ruled that the drug was subject to seizure as a misbranded drug. Judgment of condemnation and destruction was entered.

3868. Adulteration and misbranding of vitamin B_{12}. U. S. v. 105 Bottles * * *. (F. D. C. No. 33603. Sample No. 56326–L.)

LIBEL FILED: July 25, 1952, Northern District of Ohio.

ALLEGED SHIPMENT: On or about May 29, 1952, by Addison Laboratories, from Philadelphia, Pa.

PRODUCT: 105 1-ounce bottles of *vitamin B_{12}* at Mansfield, Ohio. Analysis showed that the product contained 67 percent of the declared amount of vitamin B_{12}.

LABEL, IN PART: "Vitamin B_{12} Drops 30 Micrograms per CC * * * In such doses as prescribed by a Physician * * * Mfg. For The Caldwell & Bloor Co. Mansfield, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Vitamin B_{12} * * * 30 Micrograms per CC."

Misbranding, Section 502 (a), the label statement "Vitamin B_{12} * * * 30 Micrograms per CC" was false and misleading as applied to the article, which contained less than that amount of vitamin B_{12}; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: September 12, 1952. Default decree of condemnation and destruction.

3869. Misbranding of Diaplex. U. S. v. 48 Pounds * * *. (F. D. C. No. 31964. Sample No. 29638–L.)

LIBEL FILED: November 6, 1951, Western District of Washington.

ALLEGED SHIPMENT: On or about July 10, 1951, by Diaplex Laboratories, from Carr, Colo.

PRODUCT: 48 pounds of *Diaplex* at Seattle, Wash. Samples taken from other shipments of *Diaplex* were found to consist of a species of saltbush, such as *Atriplex canescens*.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended. The article was misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: May 7, 1952. Default decree of condemnation and destruction.

3870. Misbranding of Color-Therm devices. U. S. v. 8 Devices * * *. (F. D. C. No. 32471. Sample Nos. 16471–L, 16472–L.)

LIBEL FILED: January 29, 1952, Northern District of Oklahoma; amended libel filed on or about May 19, 1952.

ALLEGED SHIPMENT: One device, including one hand applicator, was shipped from Mission, Kans., to Wewoka, Okla., and delivered during 1949 to Claremore, Okla.; in addition, 7 unlabeled devices, including 7 hand applicators,

were shipped between June and August 1951, by Fred Gerkey, from Mission, Kans., to Claremore, Okla.

PRODUCT: 8 *Color-Therm devices*, 7 unlabeled and 1 labeled, in part, "Color Therm Dr. Fred Gerkey, Mission, Kansas," including 8 hand applicators, at Claremore, Okla., in possession of Mrs. Leatha N. Foley.

The devices consisted of tubes for producing colored lights similar to the so-called neon lights, together with electrical connections required to operate them.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use for helping arthritis, rheumatism, paralysis, and aches and pains of other diseases, which were the conditions for which the device was intended. The device was misbranded when introduced into, and while held for sale after shipment in, interstate commerce.

DISPOSITION: Leatha N. Foley, claimant, filed an answer to the libel, and on or about June 19, 1952, the Government filed a motion for summary judgment, based on the pleadings and on the affidavit and deposition of Mrs. Foley, for the reason that there were no material issues of fact to be determined by the court and that the Government was entitled to a judgment as a matter of law. The court found that there was no controversial issue involved in the action and that the Government's motion for judgment should be sustained; and, accordingly, on September 30, 1952, the court entered a decree of condemnation and ordered that the devices and hand applicators be destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3871. Adulteration of peppermint leaves, spearmint leaves, hellebore root, and lobelia leaves and lobelia herb. U. S. v. 2 Bales, etc. (and 1 other seizure action). (F. D. C. Nos. 30396, 30410. Sample Nos. 24131–L to 24135–L, incl.)

LIBELS FILED: January 25 and February 1, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about October 12 and November 20, 1950, by the Smoky Mountain Drug Co., from Bristol, Tenn.

PRODUCT: 2 bales containing a total of 245 pounds of *peppermint leaves*, 4 bales containing a total of 1,060 pounds of *spearmint leaves*, 1 bale containing 318 pounds of *hellebore root*, 2 bales containing a total of 508 pounds of *lobelia leaves*, and 18 bales, each containing 190 pounds, of *lobelia herb*, at Jersey City, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the *hellebore root* consisted in whole or in part of a decomposed substance by reason of the presence of mold, and the other articles consisted in whole or in part of filthy substances by reason of the presence of rodent excreta, insects, and insect excreta; and, Section 501 (a) (2), the articles had been packed under insanitary conditions whereby they may have been contaminated with filth.

DISPOSITION: December 11, 1951. The libel proceedings against the above-mentioned products having been consolidated and the Smoky Mountain Drug Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the *spearmint leaves* and the *peppermint leaves* be destroyed and that the other products be released under bond for reconditioning, under the supervision of the Federal Security Agency.

The *spearmint leaves* and the *peppermint leaves* were destroyed, and the

other articles were reconditioned, with the result that 99 pounds of the *hellebore root*, 586 pounds of the *lobelia leaves*, and 283 pounds of the *lobelia herb* were found unfit and were destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3872. Adulteration and misbranding of estrone. U. S. v. 180 Vials * * *. (F. D. C. No. 33631. Sample No. 56320-L.)

LIBEL FILED: August 5, 1952, Northern District of Ohio.

ALLEGED SHIPMENT: On or about May 3, 1952, by the Addison Laboratories, from Philadelphia, Pa.

PRODUCT: 180 vials of *estrone* at Mansfield, Ohio. Examination showed that the amount of *estrone* per cubic centimeter for each of the 5 vials tested was as follows: 1.30 mg., 3.50 mg., 4.48 mg., 1.50 mg., and 0.74 mg.

LABEL, IN PART: "10 CC. Multiple-Dose Vial * * * Estrone U. S. P. (2.0 Mg. Per CC.)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 2.0 milligrams of estrone per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Estrone U. S. P. (2.0 Mg. Per CC.)" was false and misleading as applied to the article since the amount of estrone per cubic centimeter differed from vial to vial and varied widely above and below the declared amount.

DISPOSITION: September 8, 1952. Default decree of condemnation and destruction.

3873. Adulteration and misbranding of isopropyl alcohol rubbing compound. U. S. v. 125 Cases * * *. (F. D. C. No. 33353. Sample No. 44314-L.)

LIBEL FILED: On or about July 22, 1952, District of Rhode Island.

ALLEGED SHIPMENT: On or about June 13, 1952, by the Philadelphia Magnesia Co., from Philadelphia, Pa.

PRODUCT: 125 cases, each containing 12 1-pint bottles, of *isopropyl alcohol rubbing compound* at Providence, R. I. Examination showed that the product contained 63 percent isopropyl alcohol.

LABEL, IN PART: (Bottle) "Lee's * * * Isopropyl Alcohol Rubbing Compound 70% Isopropyl Alcohol."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Isopropyl Alcohol Rubbing Compound," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since the article contained less than 68 percent isopropyl alcohol, the minimum permitted by the standard.

Misbranding, Section 502 (a), the label statement "70% Isopropyl Alcohol" was false and misleading.

DISPOSITION: September 26, 1952. Default decree of condemnation. The court ordered that the product be delivered to the Social Welfare Department of the State of Rhode Island.

*See also Nos. 3861 (veterinary preparation), 3867, 3868, 3878 (veterinary preparation).

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3874. Misbranding of Burvidin. U. S. v. 5 Cases * * *. (F. D. C. No. 24888. Sample No. 28532–K.)

LIBEL FILED: June 15, 1948, District of Colorado.

ALLEGED SHIPMENT: On or about May 25, 1948, by the Research Laboratories, Inc., from Portland, Oreg.

PRODUCT: 5 cases, each containing 12 1-pint bottles, of *Burvidin* at Denver, Colo.

LABEL, IN PART: (Bottle) "Contents: One Pint Burvidin Active Ingredients: An aqueous extraction of the following botanicals: Plume Thistle (Carduus Lanceolatus), Burdock (Lappa), Sage (Salvia), Kola (Seed of the Nut Kola Acuminata), Dandelion (Taraxacum Officianale), Horehound (Marrubium Vulgare), Calamus (Acorus Calamus), Althea (Althaea Officianalus), Quassia (Picrasma Excelsa), Cinnamon (Cinnamonum Cassia), Ginseng (Penax Quinquefolia), Sodium Salicylate and Thiamine. Cascara Sagrada and Licorice added."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a circular entitled "Burvidin," which accompanied the article, were false and misleading. The statements represented and suggested that the article was an effective remedy for arthritis and rheumatism; that it would effect definite improvement in 80 to 90 percent of cases of acute and chronic arthritis if used for three months or longer; that it would effect definite improvement in 92 to 100 cases of arthritis, 33 to 38 cases of neuritis, 25 to 27 cases of sciatica, and 38 to 41 cases of general rheumatism; that it would effect good results in the treatment of abnormal conditions of the blood and urine; that it would effect marked improvement or complete relief of symptoms in the great majority of cases of arthritis; that it would render symptom-free 16 of 20 cases of arthritis; that it would answer the prayer of at least 75 percent of arthritics; and that it would effect improvement in 87.7 percent of cases of atrophic arthritis and in 77.7 percent of cases of hypertrophic arthritis, selected as of long duration and more hopeless, and 1 year after discontinuance of the medication all but 1 of 169 such cases would have experienced no recurrence of their arthritic syndromes. The article was not an effective remedy for arthritis and rheumatism and was not capable of fulfilling the promises of benefit stated and implied.

DISPOSITION: February 7, 1951. The case having been removed to the Northern District of Illinois and the Research Laboratories, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

3875. Misbranding of Special Formula tablets and Palmo tablets. U. S. v. 1 Drum, etc. (F. D. C. No. 33508. Sample Nos. 33779–L, 33780–L.)

LIBEL FILED: August 4, 1952, Western District of Michigan.

ALLEGED SHIPMENT: On or about November 29, 1951, from Buffalo, N. Y.

PRODUCT: 1 drum containing 52,000 *Special Formula tablets* and 200 100-tablet envelopes of *Palmo tablets* at Bellevue, Mich., in the possession of the H. D. Powers Co., together with quantities of printed matter relating to the tablets

*See also Nos. 3868, 3872, 3873.

and consisting of empty envelopes, remittance blanks, order blanks, and form letters headed "An Important Message For You" and form letters marked "Palmo #1," "Palmo #2," and "Palmo C-1."

RESULTS OF INVESTIGATION: The tablets contained in the envelopes were repacked by the consignee from the lot of *Special Formula tablets* shipped in bulk.

LABEL, IN PART: (Drum) "Special Formula Tablets * * * Each tablet contains theobromin, sodium salicylate, potassium citrate, extract buchu and extract uva ursi (beanberry)"; (envelope) "Palmo Tablets * * * Distributed by H. D. Powers Company 120 Greenwood Avenue, Battle Creek, Michigan."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the tablets, namely, in the above-mentioned printed matter accompanying the tablets, were false and misleading. The statements represented and suggested that the tablets (both lots) were an adequate and effective treatment for frequent desire to urinate and for urinary conditions due to irritation of the bladder and urinary tract. The tablets were not an adequate and effective treatment for such conditions.

DISPOSITION: September 5, 1952. Mabel Powers, owner of the product, having entered an appearance and consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the tablets, in bulk and as repackaged, and the printed matter be destroyed.

3876. Misbranding of Menestrex capsules. U. S. v. 28 Bottles, etc. (F. D. C. No. 33348. Sample No. 2614-L.)

LIBEL FILED: July 15, 1952, Southern District of Georgia.

ALLEGED SHIPMENT: On or about June 21, 1951, by the Rex Laboratory, from Nashville, Tenn.

PRODUCT: 28 12-capsule bottles of *Menestrex* and 7 25-capsule bottles of *Menestrex Extra Strength* at Augusta, Ga. Examination showed that the 12-capsule bottles of the product contained approximately 3.8 grains per capsule of quinine sulfate and 0.62 grain per capsule of potassium permanganate and that the 25-capsule bottles contained approximately 3.8 grains per capsule of quinine sulfate and 0.87 grain per capsule of potassium permanganate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Menestrex * * * For easing distress in scanty or functionally difficult menstruation * * * " was false and misleading since the article (both lots) was not efficacious to ease distress in scanty or functionally difficult menstruation.

DISPOSITION: October 29, 1952. Default decree of condemnation and destruction.

3877. Misbranding of worm syrup. U. S. v. 11 Dozen Bottles * * *. (F. D. C. No. 33094. Sample No. 8977-L.)

LIBEL FILED: April 30, 1952, Northern District of Indiana.

ALLEGED SHIPMENT: On or about February 21, 1952, by Northville Laboratories, Inc., from Northville, Mich.

PRODUCT: 11 dozen 2-ounce bottles of *worm syrup at* Fort Wayne, Ind.

LABEL, IN PART: "Hill's Peerless Worm Syrup Alcohol, 11% Contains Pink Root, Senna and Anise For Round Worms."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle and carton labels of the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for roundworms in humans, whereas the article was not effective for this purpose.

DISPOSITION: Northville Laboratories, Inc., the shipper of the product, filed an answer to the libel denying that the product was misbranded as alleged. Thereafter, the Government filed a set of interrogatories to be answered by the shipper. Answers to the interrogatories were filed on August 21, 1952, in which the shipper admitted that the product was not an effective treatment for all species of roundworms in humans. Thereafter, the shipper advised that it did not wish to contest the action further; and accordingly, a decree was entered on December 23, 1952, providing for the condemnation and the destruction of the product.

3878. Adulteration and misbranding of Whitmer's Blue Ribbon Condition Powder and misbranding of Whitmer's Eureka and Whitmer's Black Diamond Liniment. U. S. v. 15 Bags, etc. (F. D. C. No. 31709. Sample Nos. 3467–L, 3471–L, 3472–L.)

LIBEL FILED: September 14, 1951, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about October 10, 1950, and April 4, 1951, by H. C. Whitmer Co., Inc., from Columbus, Ind.

PRODUCT: 15 50-pound bags of *Whitmer's Blue Ribbon Condition Powder*, 4 cases, each containing 24 11-fluid-ounce bottles, of *Whitmer's Eureka*, and 4 cases, each containing 24 11-fluid-ounce bottles of *Whitmer's Black Diamond Liniment*, at Suffolk, Va., together with accompanying labeling consisting of various issues of a circular entitled "Whitmer Pep" which had been received by the consignee via the U. S. Mail on various dates.

Analysis showed that the *Whitmer's Blue Ribbon Condition Powder* yielded crude ash 26.95 percent, crude protein 2.55 percent, crude fat 0.54 percent, and crude fiber 18.45 percent; that the *Whitmer's Eureka* contained 3.6 percent of sodium acetate, extracts of plant drugs, 12.6 percent by volume of alcohol, and water (inspection showed that 1 tablespoonful contained more than 2 average doses of laxatives, and the directions called for 4 tablespoonfuls per day); and that *Whitmer's Black Diamond Liniment* consisted essentially of turpentine oil, pine oil, linseed oil, and camphor.

LABEL, IN PART: (Whitmer's Blue Ribbon Condition Powder) "For Horses, Cattle, Hogs & Sheep * * * Complete Chemical Analysis Moisture 9.15% Crude Ash 19.20% Crude Protein 8.90% Crude Fat 2.00% Crude Fiber 14.50% Nitrogen Free Extract 46.25% * * * This Condition Powder Is not A Food but A Medicine"; (Whitmer's Eureka) "Alcohol 15% * * * Directions—Take one tablespoonful just before meals or soon after and at bedtime"; (Whitmer's Black Diamond Liniment) "Active Ingredients: Turpentine Fractions, Linseed Oil, Camphor, Pine Oil."

NATURE OF CHARGE: *Whitmer's Blue Ribbon Condition Powder.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since it yielded more crude ash and crude fiber and less crude fat and crude protein than it was represented to contain. Misbranding, Section 502 (a), the following statements appearing in the labeling were false and misleading since the article would yield less crude protein and crude fat and more crude ash and crude fiber than declared,

and it was not effective to accomplish the purposes stated and implied: (Bag label) "Crude Ash 19.20% Crude Protein 8.90% Crude Fat 2.00% Crude Fiber 14.50%"; (circular enclosed in bag) "Crude Ash 19.20 percent, Crude Protein 8.90 percent, Crude Fat 2.00 percent, Crude Fiber 14.50 percent * * * This Condition Powder is * * * a Medicine. It tends to purify the blood, aid digestion, regulate the bowels and make healthy, fine appearing animals"; (November 10, 1949, issue of "Whitmer Pep") "The Hog * * * To feed him successfully is no easy matter as nature calls for some things that are not found in feed—a conditioner to * * * invigorate the digestive machinery so that it draws all of the nutrition out of the feed and deposits it into bone and fat. The real object in feeding the hog is to make him weigh the greatest number of pounds at market time in the shortest time with the least amount of feed. Whitmer's Blue Ribbon Condition Powder Will help you solve the hog's feeding problem. It supplies the medicine that the hog needs to make him healthy, contented and a weight gatherer. It is * * * soothing and purifying in both stomach and intestines. The hog whose system is disordered is like a hole in your grain sack—you lose every time you feed him. Whitmer's Blue Ribbon Condition Powder helps make perfect digestion and assimilation of food."

Whitmer's Eureka. Misbranding, Section 502 (a), the following statements appearing in the labeling were false and misleading since the article was not an adequate and effective treatment for the conditions stated and implied, and it would not fulfill the promises of benefit made for it: (February 22, 1951, issue of "Whitmer Pep") "Whitmer's Eureka is an alterative—Alteratives are preparations that bring about a gradual change from a diseased condition to a normal state. Eureka is a Tonic containing a combination of Herbs and Drugs known to be beneficial for the general toning up of the system * * * promoting regularity and the elimination of the poisonous wastes from the body. The ingredients in Eureka act on practically every organ in the abdominal cavity stimulating them to action * * * Buchu Leaves, Uva Ursi, Juniper Berries and Hydrangea Root are recommended for the treatment of sub-acute and chronic inflammation of the entire urinary tract including the kidneys, bladder and urinary organs. Culvers Root * * * increases the flow of the bile and stimulates the mucous glands of the intestines. * * * Gentian Root * * * aids digestion. Aloes Socotrine is * * * very beneficial in chronic constipation * * * stimulating a torpid liver. * * * Senna is * * * one of the best known drugs for treatment of chronic constipation. Sodium acetate * * * relieves irritability of the bladder." Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users since its labeling failed to warn that frequent or continued use, or use as directed on the label, may result in dependence upon laxatives to move the bowels.

Whitmer's Black Diamond Liniment. Misbranding, Section 502 (a), the following statements appearing in the labeling were false and misleading since the article was not an adequate and effective treatment for the diseases and conditions stated and implied: (May 11, 1950, issue of "Whitmer Pep") "Black Diamond. I took a cold—the doctor called it the old-fashioned grippe. * * * It caused inflammatory rheumatism. I am a shut-in for about six years. I think your Liniment has saved me this long as I had a hard fall over two years ago (when I fainted from weakness) and it also helped that";

(May 17, 1951, issue of "Whitmer Pep") "Here is a tip on Black Diamond Liniment. Mr. Vern Scott * * * had a bad big toe * * * they were going to take him to the hospital and take his leg off * * * He used Black Diamond and it healed his toe right up, so we didn't only save his toe and leg * * * 18 years before this * * * he had his toe run over by a thrashing machine. It had been sore ever since and it had mattered and run puss and had the toe all eaten away behind the toe nail, and this is what we healed up." Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against unsafe dosage and methods and duration of administration or application, in such manner and form, as are necessary for the protection of users since its labeling failed to warn that use of the article should be discontinued if excessive irritation of the skin developed, and that the user should avoid getting the drug into the eyes.

The libel covered also a number of lots of Hog Mineral and Cattle Mineral which were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: April 18, 1952. Robert Elliot Parker, Suffolk, Va., claimant, having consented to the entry of a decree, judgment of condemnation was entered. The decree provided that the products might be released under bond, conditioned that they be brought into compliance with the law, under the supervision of the Federal Security Agency; otherwise, the decree provided that they be destroyed. The products ultimately were destroyed.

DRUGS FOR VETERINARY USE*

3879. Misbranding of buttermilk feed. U. S. v. 32 Barrels, etc. (F. D. C. No. 31173. Sample No. 18783–L.)

LIBEL FILED: June 12, 1951, Southern District of Illinois.

ALLEGED SHIPMENT: On or about April 24, 1951, by the Cudahy Packing Co., from Winfield, Iowa.

PRODUCT: *Buttermilk feed.* 32 112-pound barrels and 3 90-pound steel drums at Atkinson, Ill., and 102 copies of a leaflet entitled "Hunt's Old-Fashion Condensed Buttermilk Make Your Livestock Make You Money."

LABEL, IN PART: "Hunt's Old-Fashion Buttermilk Feed Analysis Protein 8% Fat 1½% Lactic Acid 4% and Ash, Phosphates, Carbohydrates, Vitamines * * * For Animal and Poultry Feeding Made from Solids of Milk with 2% Flour added."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the barrel and drum labels and in the accompanying leaflets were false and misleading. These statements represented and suggested that the drug would be effective to aid in the assimilation and digestion of other feeds; to help save pigs, chicks, and turkeys; as a conditioner and tonic; to make hens "shell out" more eggs; to make broilers earlier from little chicks and make hogs sooner from little pigs; to keep hogs healthy; to prevent and treat the disease necrotic enteritis of pigs; and to prevent coccidiosis of poultry. The product was not effective for such purposes.

DISPOSITION: January 25, 1952. The shipper, claimant, having consented, judgment of condemnation was entered and the court ordered that the product be released under bond to be relabeled under the supervision of the Food and Drug Administration.

*See also Nos. 3861, 3878.

3880. Misbranding of Stock Powder and Poultry Mineral. U. S. v. 78 Bags, etc. (F. D. C. No. 33498. Sample Nos. 48858–L, 48859–L.)

LIBEL FILED: August 21, 1952, District of Minnesota.

ALLEGED SHIPMENT: On or about May 6 and during June 1951, by James J. Doty Co., Ltd., from Shenandoah, Iowa.

PRODUCT: 78 50-pound bags of *Stock Powder* and 3 50-pound bags of *Poultry Mineral* at Luverne, Minn., together with a number of leaflets entitled "White Scours" containing statements relating to the *Stock Powder* and a number of booklets entitled "The Key To Success Economy Poultry Mineral" relating to the *Poultry Mineral*.

LABEL, IN PART: (Bag) "Economy Stock Powder Ingredients: Sulphate of Soda, Sulphur, Bi-Carbonate of Soda, Calcium Carbonate, Charcoal, American Wormseed, Iron Oxide, Manganese Sulphate, Hypo-Sulphite of Soda, Poke Root, Blood Root, Oil of Wormseed, Potassium Iodide. Calcium (Ca) Not more [or] less than 2.5% Iodine (I) Not less than .0125%" and "Economy Poultry Mineral Ingredients: Sulphate of Soda, Calcium Carbonate from limestone, Sulphur, Soft Phosphate with Colloidal Clay, Bi-Carbonate of Soda, Charcoal, Tobacco, American Wormseed, Iron Oxide, Manganese Sulphate, Hypo-Sulphite of Soda, Poke Root, Blood Root, Oil of Wormseed, Potassium Iodide. Calcium (Ca) Not more [or] less than 10% Phosphorus (P) Not less than .8% Salt (NaCl) None, Iodine (I) Not less than .0125%."

NATURE OF CHARGE: *Stock Powder.* Misbranding, Section 502 (a), certain statements in the leaflet entitled "White Scours" accompanying the article were false and misleading. The statements represented and suggested that the article was effective in preventing and curing white scours in pigs, whereas the article was not effective for this purpose.

Poultry Mineral. Misbranding, Section 502 (a), certain statements in the booklet entitled "The Key To Success Economy Poultry Mineral" accompanying the article were false and misleading. The statements represented and suggested that the article was effective as a worm expeller; that it was effective to overcome morbid processes; that it was effective as a tonic; and that it was effective to prevent and to cure roup, chicken pox, "sore head" in poultry, and blackhead in turkeys. The article was not effective for such conditions and diseases.

Further misbranding, Section 502 (a), the designation "Minerals" appearing in the labeling of the *Poultry Mineral* was false and misleading as applied to a product containing ingredients that are not minerals.

DISPOSITION: October 15, 1952. Default decree of destruction.

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U. S. GOVERNMENT PRINTING OFFICE: 1953

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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3881–3900

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*
WASHINGTON, D. C., *June 23, 1953.*

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DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3881. Misbranding of Seconal Sodium capsules, phenobarbital tablets, capsules of pentobarbital sodium and aspirin, and methamphetamine hydrochloride tablets. U. S. v. Edward J. Lotz, Jr. (Eddie's Drug Store). Plea of nolo contendere. Fine, $260. (F. D. C. No. 32733. Sample Nos. 16048–L to 16051–L, incl., 16053–L, 16063–L, 16064–L, 16066–L.)

INFORMATION FILED: October 16, 1952, Eastern District of Oklahoma, against Edward J. Lotz, Jr., trading as Eddie's Drug Store, Ardmore, Okla.

ALLEGED VIOLATION: On or about September 29 and October 10, 12, 15, and 16, 1951, while a number of *Seconal Sodium capsules, phenobarbital tablets, capsules of pentobarbital sodium and aspirin,* and *methamphetamine hydrochloride tablets* were being held for sale at Eddie's Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *phenobarbital tablets, capsules of pentobarbital sodium and aspirin,* and *methamphetamine hydrochloride tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged drugs, with the exception of the *methamphetamine hydrochloride tablets,* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of these drugs failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the repackaged *methamphetamine hydrochloride tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: On December 4, 1952, the defendant filed a motion to dismiss the counts involving the dispensing of the *Seconal Sodium capsules* and entered a plea of nolo contendere to the counts charging the dispensing of the other drugs involved. On December 22, 1952, the court overruled the motion to dismiss, after which the defendant entered a plea of nolo contendere to the counts involving the *Seconal Sodium capsules.* On December 22, 1952, the court imposed a fine of $260 against the defendant.

3882. Misbranding of Seconal Sodium capsules, tablets of phenobarbital and mannitol hexanitrate, methamphetamine hydrochloride tablets, and liquid mixture of phenobarbital and thiamine. U. S. v. James E. Martin (Martin Drug Co.). Plea of nolo contendere. Fine, $210. (F. D. C. No. 32736. Sample Nos. 15599–L to 15602–L, incl., 15609–L, 15613–L, 15614–L.)

INFORMATION FILED: October 16, 1952, Eastern District of Oklahoma, against James E. Martin, trading as the Martin Drug Co., Ardmore, Okla.

ALLEGED VIOLATION: On or about September 29 and October 10, 12, and 15, 1951, while quantities of *Seconal Sodium capsules, tablets of phenobarbital and mannitol hexanitrate*, and a *liquid mixture of phenobarbital and thiamine* were being held for sale at the Martin Drug Co., after shipment in interstate commerce, the defendant caused quantities of such drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded; and, on or about October 15, 1951, while a number of *methamphetamine hydrochloride tablets* were being held for sale, after shipment in interstate commerce, the defendant caused one bottle of such tablets to be dispensed in the original bottle in which the tablets had been shipped in interstate commerce, without the prescription of a physician, which act resulted in such tablets being misbranded.

NATURE OF CHARGE: *Methamphetamine hydrochloride tablets.* Misbranding, Section 502 (f) (1), the labeling of the tablets bore no directions for use. (The bottle in which the tablets were shipped in interstate commerce bore no directions for use since it was exempted from such requirement by the label statement "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendant in dispensing the drug without a physician's prescription, however, caused the exemption to expire.)

Seconal Sodium capsules, tablets of phenobarbital and mannitol hexanitrate, and a *liquid mixture of phenobarbital and thiamine.* Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents. Further misbranding, Section 502 (d), the repackaged drugs contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the name, and quantity or proportion of each derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

DISPOSITION: On December 4, 1952, the defendant filed a motion for dismissal of counts 1 through 4 of the information relating to the *Seconal Sodium capsules* and for a plea of nolo contendere to the remaining 3 counts of the information involving the other drugs described above. On December 22, 1952, the motion to dismiss was overruled, and the defendant entered a plea of nolo contendere to counts 1 through 4. On the same day, the court imposed a fine of $210 against the defendant.

3883. Misbranding of methyltestosterone tablets, thyroid tablets, ergot and apiol capsules, dextro-amphetamine sulfate tablets, tablets of phenobarbital and mannitol hexanitrate, and tablets of caffeine and ergot alkaloids. U. S. v. Fred C. Blalock (Corner Drug Store). Plea of nolo contendere. Fine, $600. (F. D. C. No. 32738. Sample Nos. 16070-L, 16072-L, 16074-L, 16076-L, 16078-L, 16080-L.)

INFORMATION FILED: October 16, 1952, Eastern District of Oklahoma, against Fred C. Blalock, trading as the Corner Drug Store, Madill, Okla.

ALLEGED VIOLATION: On or about October 10, 12, 15, and 16, 1951, while quantities of *methyltestosterone tablets, thyroid tablets, ergot and apiol capsules, dextro-amphetamine sulfate tablets, tablets of phenobarbital and mannitol*

hexanitrate, and *tablets of caffeine and ergot alkaloids* were being held for sale at the Corner Drug Store, after shipment in interstate commerce, the defendant caused one bottle of *methyltestosterone tablets* to be dispensed in the original bottle in which the tablets had been shipped in interstate commerce, without the prescription of a physician; and the defendant caused various quantities of the other drugs to be repacked and dispensed without a physician's prescription, which acts of the defendant resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the *methyltestosterone tablets* failed to bear adequate directions for use. (The bottle in which the tablets had been shipped in interstate commerce bore no directions for use since it was exempted from such requirement by the label statement "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendant in dispensing the drug without a physician's prescription, however, caused the exemption to expire.)

Further misbranding, Section 502 (b) (1), the repackaged *tablets of caffeine and ergot alkaloids* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *tablets of phenobarbital and mannitol hexanitrate* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the labeling of the tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *ergot and apiol capsules* and the *tablets of caffeine and ergot alkaloids* failed to bear labels containing the common or usual name of each active ingredient of the drugs; Section 502 (f) (1), all of the repackaged drugs failed to bear labeling containing adequate directions for use; and, Section 502 (f) (2), the repackaged *ergot and apiol capsules* and *tablets of caffeine and ergot alkaloids* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: November 19, 1952. A plea of nolo contendere having been entered, the court fined the defendant $600.

3884. Adulteration and misbranding of dextro-amphetamine sulfate tablets and amphetamine sulfate tablets and misbranding of Femo pills, Super Femo pills, Femo perles, and ergot and apiol capsules. U. S. v. Saul M. Lipton (Kumfort Drug Products Co.). Plea of guilty. Fine, $1,200. (F. D. C. No. 33723. Sample Nos. 3111–L, 3121–L, 7176–L, 7181–L to 7184–L, incl., 20953–L, 20988–L.)

INFORMATION FILED: October 1, 1952, Northern District of Ohio, against Saul M. Lipton, trading as the Kumfort Drug Products Co., Cleveland, Ohio.

ALLEGED SHIPMENT: On or about July 14 and August 3, 1950, and January 29, February 3, April 9, and May 12 and 21, 1951, from the State of Ohio into the District of Columbia and the States of Texas and Pennsylvania, of a number

of unlabeled bottles of *dextro-amphetamine sulfate tablets* (represented as 4.62-milligram and 5-milligram strength) and *amphetamine sulfate tablets* (represented as 10-milligram strength), a number of bottles of *ergot and apiol capsules*, and a number of boxes of *Femo pills*, *Super Femo pills*, and *Femo perles*.

LABEL, IN PART: "Marlene Dee Femo Pills [or "Super Femo Pills" or "Femo Perles"] * * * Manufactured for Marlene Laboratories Cleveland, Ohio," and "Ergot and Apiol Capsules."

NATURE OF CHARGE: *Dextro-amphetamine sulfate tablets* and *amphetamine sulfate tablets*. Adulteration, Section 501 (d) (2), tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate had been substituted for *dextro-amphetamine sulfate tablets*, and tablets containing not more than 6.3 milligrams of amphetamine sulfate had been substituted for 10-milligram *tablets of amphetamine sulfate*. Misbranding, Sections 502 (b) (1) and (2), the tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f), the labeling of the tablets failed to bear (1) adequate directions for use and (2) such adequate warnings against use in those pathological conditions or by children where their use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users. Further misbranding, Section 502 (e) (2), the *dextro-amphetamine sulfate tablets* (4.62 and 5 milligrams) were not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient contained in the tablets; and, Section 502 (i) (3), the *dextro-amphetamine sulfate tablets* (4.62 and 5 milligrams) consisted of tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate and were offered for sale under the name of another drug, namely, *dextro-amphetamine sulfate tablets*.

Ergot and apiol capsules. Misbranding, Section 502 (b) (1), the capsules failed to bear a label containing the name and place of business of the manufacturer, packer or distributor; Section 502 (e) (2), the capsules were not designated in an official compendium and were fabricated from two or more ingredients, and their label failed to bear the common or usual names of each active ingredient; and, Section 502 (f) (1), the labeling of the capsules failed to bear adequate directions for use.

Femo pills, Super Femo pills, and Femo Perles. Misbranding, Section 502 (a), the label statement "Containing * * * Emmenogogues," displayed upon the boxes containing the articles, was false and misleading since it represented and suggested that the articles were effective as an emmenagogue, whereas the articles were not effective as an emmenagogue. Further misbranding, Section 502 (e) (2), the *Femo perles* were not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients, and their label failed to bear the common or usual name of each active ingredient.

DISPOSITION: October 31, 1952. A plea of guilty having been entered, the court imposed a fine of $1,200.

3885. Misbranding of ozone generators. U. S. v. 16 Devices, etc. Answer filed on behalf of owners. Motion for summary judgment filed on behalf of Government. Decree of condemnation. (F. D. C. No. 33532. Sample Nos. 14593–L to 14607–L, incl.)

LIBEL FILED: August 22, 1952, District of New Mexico.

ALLEGED SHIPMENT: The devices were shipped by United Ozone, Inc., from Fullerton and Paramount, Calif., between the dates of November 1, 1951, and July 1, 1952, to Mrs. M. M. Stubblefield, Hobbs, N. Mex., and a number of pamphlets relating to the devices were shipped to Mrs. Stubblefield by J. H. Effenberg, from a place unknown in California.

PRODUCT: 16 *ozone generators* at Hobbs and Eunice, N. Mex., together with a number of pamphlets entitled "Ozone Therapy By O. M. Justice, M. D.," "Calozone Generator," and "Ozone God's Gift to Humanity."

The device consisted of a group of eight tubes which, when activated by an electric current, would fluoresce with production of ozone in the surrounding air. The pamphlets were given or loaned by Mrs. Stubblefield to each person purchasing from her one of the devices.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned pamphlets which accompanied the devices were false and misleading. The statements represented and suggested that ozone generated by the device would prevent disease and act as a specific in many diseases; that it would be effective for adenitis, swelling of the breasts, angina pectoris, alopecia, falling of the hair, arthritis, asthma, arteriosclerosis, backache, biliousness, bronchitis, bursitis, colitis, colds, sore chest, constipation, dandruff, deafness, erysipelas, earache, eczema, high blood pressure, indigestion, jaundice, leucorrhea, mumps, nervousness, pleurisy, prostate trouble, pneumonia, pelvic disturbances, psoriasis, quinsy, sore throat, rheumatism, rectal disturbances, sleeplessness, sinus trouble, tuberculosis, and varicose veins; that it would protect one and one's family from air-transmitted diseases which injure and kill hundreds and thousands of children and adults every year; that it would prevent radiation disease; that it would be effective for skin burn, eye injury, kidney disturbances, heart attack, infections of the pleura, peritoneum, pelvis renalis, bladder, urethra, and intestines, chlorosis, anemia, nervous prostration, chronic nasopharyngeal catarrh, anemia in tuberculosis of cutis, chronic lead poisoning, pertussis, diphtheria, scarlet fever, and other infectious diseases, pernicious anemia, cardiovascular-renal disease, consumption, catarrh, hay fever, dyspepsia, headaches, inactive liver and kidneys, syphilis, neurasthenia, melancholia, bronchiectasis, and gas poisoning; and that in combination with olive oil, it would be effective in Bright's disease, abscesses, and influenza. The ozone generated by the device would not be effective for such purposes, and it would not fulfill the promises of benefit stated and implied. The device was misbranded in the above respect while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use since its labeling bore no directions for use. The device was misbranded in this respect when introduced into and while in interstate commerce.

DISPOSITION: Following the filing of the libel, letters were addressed by the United States attorney to each of the owners of the devices at Hobbs and Eunice, N. Mex., asking them to hold the devices for seizure. Thereafter, a petition was received from the owners requesting that no order or seizure be

issued. An order to show cause why the devices which were the subject of seizure should not be condemned was then issued, and a hearing before the court on the matter was set for October 3, 1952.

On October 2, 1952, the owners of the devices filed a "Response to Order to Show Cause and Answer to Libel of Information," denying that the devices were misbranded and alleging the following defenses: (1) that the court had no jurisdiction for the reasons that the libel did not allege the devices were dangerous to the owners, that the pamphlets were shipped separately and did not accompany the devices so as to constitute one continuous shipment, and that the libel failed to allege the pamphlets described the devices and that the owners were defrauded; (2) that the owners had bought the devices for purifying and reconditioning their homes and had obtained almost instant relief from their disabilities; and (3) that the owners had received no harmful effects, that the devices were beneficial in treating the ailments alleged in the libel, and that the owners did not buy the devices by reason of the statements contained in the pamphlets.

On October 3, 1952, argument was heard by the court on the legal defenses raised by the owners' response, at the conclusion of which the court announced that it would take such matters under advisement and set November 24, 1952, as the date for the trial of the case.

A motion for summary judgment was filed on October 17, 1952, on behalf of the Government on the ground that there was no genuine issue as to any material fact relating to the charge of misbranding under Section 502 (f) (1), as alleged in the libel.

On November 24, 1952, after consideration of the affidavits filed on behalf of both parties and of the briefs and arguments of counsel, the court ruled in favor of the Government and entered the following judgment:

HATCH, *District Judge:* "The United States of America, libelant, having filed a motion for summary judgment, and both parties having filed affidavits; and the Court having heard argument on said motion and having ruled as follows:

(1) The articles under seizure are devices within the meaning of 21 U. S. C. 321 (h) (1); and
(2) The statement in the labeling of a "device" that a physician be consulted does not constitute "adequate directions for use" within the meaning of 21 U. S. C. 352 (f) (1); and
(3) To constitute "adequate directions for use" within the meaning of 21 U. S. C. 352 (f) (1), the directions in the labeling of a device must be sufficient within themselves without reference to any outside source; and
(4) There is no genuine issue of fact; and
(5) The devices under seizure were misbranded in violation of 21 U. S. C. 352 (f) (1) when they were introduced into and while in interstate commerce; and
(6) No costs will be assessed since this case is disposed of on motion before trial;

"IT IS THEREFORE ORDERED, ADJUDGED, and DECREED that the devices under seizure are hereby condemned pursuant to 21 U. S. C. 334 (a); and

"IT IS FURTHER ORDERED that the United States Marshal release said devices to a representative of the United States Food and Drug Administration for use in investigational and other enforcement purposes."

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3886. Adulteration of angelica root. U. S. v. 2 Bales * * *. (F. D. C. No. 33537. Sample No. 38384–L.)

LIBEL FILED: On or about August 26, 1952, Southern District of New York.

ALLEGED SHIPMENT: On or about December 15, 1950, from Belgium.

PRODUCT: 2 bales, each containing 45 pounds, of *angelica root* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insect-damaged material and insect excreta. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: October 2, 1952. Default decree of condemnation and destruction.

3887. Adulteration of colchicum seed. U. S. v. 9 Bags * * *. (F. D. C. No. 33530. Sample No. 38377–L.)

LIBEL FILED: On or about August 17, 1952, Southern District of New York.

ALLEGED SHIPMENT: On or about December 8, 1950, from Jersey City, N. J.

PRODUCT: 9 100-pound bags of *colchicum seed* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the product consisted in whole or in part of a filthy substance by reason of the presence of insects. The product was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 19, 1952. Wm. E. Martin, New York, N. Y., having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for reconditioning by fumigating, sifting, and blowing so as to render the product fit for human consumption.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3888. Adulteration and misbranding of Lynntestro AQ. U. S. v. 114 Vials * * *. (F. D. C. No. 33515. Sample Nos. 41373–L, 41377–L.)

LIBEL FILED: On or about August 11, 1952, District of New Jersey.

ALLEGED SHIPMENT: On or about May 22, 1952, by the Addison Laboratories, from Philadelphia, Pa.

PRODUCT: 114 vials of *Lynntestro AQ* at Camden, N. J.

LABEL, IN PART: (Vial) "10 cc Multiple-Dose Vial Lynntestro AQ Aqueous Macrosuspension * * * Sterile—Intramuscular."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since the article was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterile" was false and misleading.

DISPOSITION: October 23, 1952. Default decree of condemnation and destruction.

*See also No. 3884.

3889. Adulteration of epinephrine injection. U. S. v. 9 Cartons * * *. (F. D. C. No. 33563. Sample No. 49607–L.)

LIBEL FILED: On or about September 3, 1952, Southern District of New York.

ALLEGED SHIPMENT: On or about March 20 and May 26, 1952, from Chicago, Ill.

PRODUCT: 9 cartons, each containing 100 ampuls, of *epinephrine injection*, at New York, N. Y.

LABEL, IN PART: (Ampul) "1 cc. – Sterile Epinephrine Injection 1:1000 U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Epinephrine Injection," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the strength of the article differed from the official standard since it contained not more than .08 gram of epinephrine in each 100 cc. (The United States Pharmacopeia requires that epinephrine injection contain not less than .09 gram of epinephrine in each 100 cc.) The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 26, 1952. Default decree of condemnation. The court ordered that a portion of the article be delivered to the Federal Security Agency and that the remainder be destroyed.

3890. Adulteration and misbranding of Acephenacyl No. 5. U. S. v. 26,000 Tablets * * *. (F. D. C. No. 34067. Sample No. 34537–L.)

LIBEL FILED: October 8, 1952, Southern District of Illinois.

ALLEGED SHIPMENT: On or about November 28, 1951, from St. Louis, Mo.

PRODUCT: 26,000 tablets of *Acephenacyl No. 5*, repackaged in 1,000- and 500-tablet bottles, at Peoria, Ill.

LABEL, IN PART: "Acephenacyl No. 5 * * * Acetylsalicylic Acid 2 Grs."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since it contained less acetylsalicylic acid per tablet than the 2 grains declared on its label.

Misbranding, Section 502 (a), the label statement "Acetylsalicylic Acid 2 Grs." was false and misleading as applied to the article, which contained less than 2 grains of aspirin.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: November 13, 1952. Default decree of condemnation and destruction.

3891. Adulteration and misbranding of burn ointment. U. S. v. 170 Boxes * * *. (F. D. C. No. 33894. Sample No. 14044–L.)

LIBEL FILED: October 2, 1952, District of Colorado.

ALLEGED SHIPMENT: On or about July 17, 1952, by A. E. Halperin Co., Inc., from Boston, Mass.

PRODUCT: 170 boxes, each containing 2 tubes, of *burn ointment* at Remaco, Colo. Examination showed that the article was not an ointment, but that it was a thin mucilage-like fluid with some suspended solid material. Analysis showed that the article contained phenol, glycerin, and tannic acid.

LABEL, IN PART: (Box) "2½ Oz. Tannic Acid Ointment Burn Ointment Unit No. 7 * * * *"; (tube) "Halco Tannic Acid Salve Tannic Acid 5%

in Water Soluble Base Glycerine and ½ of 1% Phenol Added Net Weight Approx. ¾ Ounce."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess since it did not have the consistency of an ointment.

Misbranding, Section 502 (a), the designation "Burn Ointment" and the quantity of contents statement "2½ Oz." appearing on the box label were false and misleading as applied to the article, which was not an ointment and which contained 2 ¾-ounce tubes.

DISPOSITION: December 11, 1952. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3892. Misbranding of crude drugs. U. S. v. 100 Pounds, etc. (F. D. C. No. 32207. Sample Nos. 26813–L, 26815–L, 26816–L, 26818–L to 26821–L, incl., 26823–L to 26829–L, incl., 26831–L to 26837–L, incl., 26843–L, 26844–L, 26849–L, 26850–L, 26852–L, 26855–L, 26857–L to 26859–L, incl.)

LIBEL FILED: On or about December 17, 1951, Northern District of California.

INTERSTATE SHIPMENT: Various quantities of *crude drugs* were shipped in interstate commerce to San Francisco, Calif., as follows: Between 1934 and September 22, 1950, from Hamburg, Germany; between 1943 and September 22, 1950, from Jersey City, N. J.; on or about November 21, 1941, from St. Louis, Mo.; and on or about February 22, 1949, from Deux-Acren, Belgium.

PRODUCT: 1,190 pounds of *crude drugs* at San Francisco, Calif., together with approximately 5,000 copies of a book entitled "Herbs for Health."

RESULTS OF INVESTIGATION: The books entitled "Herbs for Health" were not shipped with the drugs but were printed locally and contained statements relating to the drugs. The designations of the drugs and the statements in the booklets relative thereto are set forth in the "Nature of Charge."

NATURE OF CHARGE: Misbranding while held for sale after shipment in interstate commerce, Section 502 (a), the following statements relating to the drugs and appearing in the book "Herbs for Health" were false and misleading since they represented and suggested that the drugs were effective in the treatment of the conditions stated and implied and were capable of fulfilling the promises of benefit made for them, whereas, they were not effective in the treatment of such conditions and were not capable of fulfilling such promises:

Agrimonium Eupatorium Herba (agrimony), (page 138). "Agrimony * * * has a tendency of invigorating the functions of stomach, liver and bowels, eliminating foul matter from the system. It is also highly recommended in the treatment of stones and gravel in kidneys and bladder. As a gargle the decoction is very effective in soreness and inflammation of mouth and throat."

Arnica Fl. (arnica flowers), (page 139). "In this country Arnica is mostly used in the form of the Tincture as an external application in Sprains, Bruises, to relieve inflammation and swelling. In Europe, however, it is also used internally in the treatment of Gout, Rheumatism and Feverish conditions."

Betula Lenta Folia (birch flowers), (page 140). "Birch * * * The

*See also Nos. 3884, 3885, 3888, 3890, 3891.

Leaves * * * Has been highly recommended in complaints of the urinary organs, inflammation or gravel in kidneys and bladder."

Scutelleria (skullcap), (page 162). "Skullcap * * * has a very beneficial influence on the nervous system, soothing and strengthening it. It is especially recommended in restlessness, nervous irritability, wakefulness, nervous weakness, convulsions and fits"; (page 196) "Skullcap-Ton. Ner. A'spa. * * *" interpreted on pages 129 to 131 to mean "Ton. Tonic-Producing an increase in the tone of the system. Ner.—Nervine—An agent calming nervous excitment. A'spa.—Anti-Spasmodic—Counteracting or preventing spasms."

Arctium Lappa Radix (burdock root), (page 143). "Burdock Root * * * is known for its blood cleansing properties and is, therefore, used in * * * blood remedies. Skin eruptions, due to impurities in the blood, yield quickly to its cleansing properties. It is extensively used in scrofulous, hepatic, rheumatic and cutaneous diseases."

Triticum Repens (couch grass), (page 177). "Couch Grass * * * Nep." interpreted on page 130 to mean "Nep.—Nephritic—An agent useful in kidney complaints"; (page 136) "Nephritics: Agents useful in kidney complaints * * * Couch Grass Root"; (page 147) "Dog Grass—Couch Grass * * * The Root * * * is very valuable in disorders of Kidneys and Bladder and in urinary troubles that originate with colds and catarrh in these organs. It induces the proper flow of the urine, tends to relieve painful, scanty, but frequent urination. Its blood purifying properties are also quite pronounced."

Vaccinum Myrtilla Fructus (dried huckleberries or bilberries), (page 183). "Huckleberries * * * A'sep" interpreted on page 129 to mean "A'sep.—Anti-Septic—Preventing or counteracting decay, or the formation of pus"; (page 171) "Bilberries, Black * * * A'sco" interpreted on page 129 to mean "A'sco—Anti-Scorbutic—Preventing or relieving scurvy"; (page 139) "Bilberry or Huckleberry * * * The berries are an excellent remedy in diarrhea and their juice mixed with water affords a very refreshing drink in all feverish conditions."

Chimaphila Umb Folia (pipsissewa), (page 159). "Princess Pine (Pipsissewa) * * * These leaves are extensively used in disorders of the urinary organs; especially to relieve irritation and catarrhal conditions of Kidneys and Bladder, for the reduction of uric acid and against deposits of stones and gravel."

Plantago Herba (plantain), (page 191). "Plantain Herb-Pect. A'sept. * * * Vul." interpreted on pages 129 to 131 to mean "A'sep—Anti-Septic—Preventing or counteracting decay, or the formation of pus. * * * Pec.—Pectoral—A remedy for diseases of chest and lungs * * * Vul.—Vulnerary—An agent favoring the healing of wounds and cuts"; (page 157) "Plantain * * * relieves coughs, bronchitis, hoarseness and loosens catarrhal obstructions from bronchial tubes and lungs. It is also used externally as a poultice on old, badly healing ulcers and sores, inflamed eyes and muscles."

Phytolacca Dec. Radix (poke root), (page 158). "Poke Root * * * This root has a very favorable influence on the glandular system, inciting and increasing its action. Regulates liver and bowels and cleans the blood. It is, therefore, highly valued in rheumatic conditions and affections of the skin due to impurities in the blood."

Hypericum (St. John's Wort), (page 197). "St. Johnswort * * * Pect." interpreted on page 130 to mean "Pec.—Pectoral—A remedy for diseases of chest and lungs"; (page 163) "St. John's Wort * * * This herb exerts a very beneficial influence on the nervous system, urinary organs and liver. It is

especially highly recommended in the bed wetting of children and weakness of the bladder."

Shepherds Purse Herb, (page 162). "Shepherd's Purse * * * Its decoction is used to arrest bleeding of all kinds, hemorrhages of the lungs, stomach and bowels. It is also extensively used for excessive menstrual flow."

Ictodes (skunk cabbage), (page 196). "Skunk Cabbage Root * * * A'epi" interpreted on page 129 to mean "A'epi.—Anti-Epileptic—Opposed to epilepsy, relieving fits."

Aletris (true unicorn root), (page 200). "Unicorn, True Root * * * Aph." interpreted on page 129 to mean "Aph.—Aphrodisiac—Stimulating the sexual passion."

Trillium Pend. (bethroot), (page 171). "Beth Root—F'com Aph." interpreted on pages 129 and 130 to mean "Aph.—Aphrodisiac—Stimulating the sexual passion * * * F. Com.—Female Complaint—Disease peculiar to woman"; (page 133) "Anti-Spasmodics: Counteracting or preventing spasms"; (page 139) "Beth Root * * * A highly prized Indian remedy to stop bleeding from lungs, bowels, kidneys, and to arrest excessive menstrual flow. In coughs, bronchitis and asthmatic conditions, it is said to give quick and certain relief."

Boneset, (page 173). "Boneset Herb-Feb." interpreted on page 130 to mean "Feb.—Febrifuge—An agent that lessens fever"; (page 141) "Boneset * * * Its fever reducing * * * properties makes this plant one of the most valuable herbs in colds and fevers. Catarrhal conditions due to colds yield quickly to the healing effect of this wonderful plant. It is also highly recommended as a cold preventive"; (page 135) "Febrifuges: Agents that reduce fever * * * Boneset Herb."

Rhamnus Frangula (buckthorn bark), (page 173). "Buckthorn Bark-Hep" interpreted on page 130 to mean "Hep.—Hepatic—Promoting the action of the liver and the flow of bile"; (page 135) "Febrifuges: Agents that reduce fever * * * Buckthorn Bark."

Matricaria Anthemis Nobilis (Hungarian chamomile flowers), (page 144). "Chamomile * * * The Flowers * * * Its soothing, pain relieving effect in stomach disorders and menstrual irregularities make it a most valued medicinal agent, especially in such cases where these troubles are of a nervous origin. The infusion is used externally with good results in compresses to relieve pain and swelling."

Camomilla Romana (Roman chamomile flowers), (page 132). "Antiperiodics: Medicines preventing the recurrence of periodic disturbances and irregularities * * * Roman Chamomile."

Dioscorea (colic root), (page 176). "Colic Root—* * * F'reg." interpreted on page 130 to mean "F'reg.—Female Regulator—An agent that regulates the menstrual flow."

Viburnum Opulus (cramp bark), (page 177). "Cramp Bark—A'per." interpreted on page 129 to mean "A'per.—Anti-Periodic—Preventing the recurrence of periodic disturbances and irregularities"; (page 146) "Cramp Bark * * * is very effective in relieving cramps and spasms of all kinds. As it also exerts a decided influence upon the generative organs, it is especially useful in menstrual cramps and pains, giving tone and energy to the Uterus. It is claimed that its use during pregnancy has a tendency of diminishing miscarriage, especially if used with equal parts of Blazing Star Root"; (page 132) "Antiperiodics: Medicines preventing the recurrence of periodic disturbances and irregularities * * * Cramp Bark."

Vaccinum Myrtillus (bilberry or huckleberry leaves), (page 183). "Huckleberries, Leaves * * * in Diabetes"; (page 139) "Bilberry or Huckleberry * * * The leaves are considered one of the best and most reliable remedies in Diabetes and also in disorders of the Urinary Organs, in gravel and stones of the Kidney and Bladder."

Hydrangea (hydrangea root or sevenbarks root), (pages 183 and 195). "Hydrangea Root—A'lith * * * Seven Barks Root — A'lith" interpreted on page 129 to mean "A'lith—Antilithic—Preventing the formation of gravel or stones"; (page 132) "Antilithics: Medicines preventing the formation of gravel and stones * * * Seven Barks Root * * * Hydrangea Root."

Quercus Rubra (red oak bark), (page 154). "Oak bark possesses strong * * * antiseptic properties. Internally it is used * * * to stop mucous discharge and bleeding. * * * in the form of a decoction, it is used as a gargle for sore throat and as an injection for leucorrhea * * * Poultices of the ground bark are used with good results in ulcers and badly healing sores"; (page 133) "Antiseptics: Agents preventing or counteracting decay, or the formation of pus * * * Oak Bark (red)."

Berberis Aquifolium (Oregon grape root), (page 189). "Oregon Grape Root-Hep. * * * A'rheu" interpreted on pages 129 and 130 to mean "A'Rhe.—Anti-Rheumatic—Correcting and relieving rheumatism * * * Hep.—Hepatic—Promoting the action of the liver and the flow of bile"; (page 156) "Oregon Grape Root Berberis Aquifolium * * * Very valuable in jaundice, sluggishness of the liver and bowels, and rheumatic conditions. Increases the power of the digestive organs and aids the assimilation of food. Its blood cleansing properties make it also a much used remedy in skin diseases, scrofula, pimples and boils"; (page 134) "Depuratives: Removing impurities, cleaning the blood * * * Oregon Grape Root."

Anemone Pratensis (Pulsatilla), (page 191). "Pulsatilla Herb-Heart Sedative."

Aralia Racemosa (spikenard root), (page 196). "Spikenard, American Root—Dep. Pect." interpreted on page 130 to mean "Dep.—Depurative—Removing impurities, cleansing the blood. * * * Pec.—Pectoral—A remedy for diseases of chest and lungs."

Viola Odorato Flores (violet flowers), (page 200). Violet Flowers—Dep. * * * Lit. Dis." interpreted on page 130 to mean "Dep.—Depurative—Removing impurities, cleansing the blood. * * * Lit.—Lithotripic—An agent dissolving stones in the urinary organs. * * * Dis.—Discutient—Dispersing tumors and ulcers."

Art. Absint Herba (wormwood herb), (page 202). "Wormwood Herb—Hep." interpreted on page 130 to mean "Hep.—Hepatic—Promoting the action of the liver and the flow of bile"; (page 168) "Wormwood Artemisia Absinthium * * * The Herb * * * Whenever the digestive organs are in a debilitated condition and the liver is sluggish, this herb has no equal in its prompt and reliable action. It promotes the flow of bile in jaundice and other liver complaints. In fever and diarrhea it also gives excellent results. Its reliable action in worms of stomach and bowels gave it its name, but as its action is powerful, it should, however, be correctly dosed. Externally it is used as a poultice for swellings, inflammation, bruises and sprains."

Rumex Crispus (yellow dock root), (page 202). "Yellow Dock Root * * * Dep." interpreted on page 130 to mean "Dep.—Depurative—Removing impurities, cleansing the blood"; (page 168) "Yellow Dock Rumex Crispus * * * The Root * * * The blood cleansing properties of this root make it an outstanding

remedy in all diseases due to impurities in the blood. It is, therefore, especially valuable in skin eruptions, eczema, pimples, boils, rheumatic and scrofulous conditions."

The book entitled "Herbs for Health," by Dr. Otto Mausert, accompanied the drugs as labeling, while the drugs were held for sale after shipment in interstate commerce, by reason among others of the association of the book with the drugs, the sale of the book as an inducement for the purchase of the drugs, and the use of the book as part of a distributional scheme in connection with the sale of combinations of the drugs (formulas) for the symptoms, diseases, and conditions for which the drugs were recommended in the book. Illustrative of such uses were:

That Nature's Herb Co., a California corporation, was engaged at San Francisco in selling, among other things, the *crude herbs* hereinbefore described and the book "Herbs for Health" by Dr. Otto Mausert.

That Nathan Podhurst was president of the company, Dr. Mausert's widow (now M. M. Yons) was vice president, and Margaret P. Gross (Mrs. Fred Leonard and Mrs. Yon's sister) was the firm's attorney.

That the book "Herbs for Health" contained a great many combinations of crude herbs, or formulas, which were numbered, and each of the numbered formulas, when prepared as a brew as directed, was recommended for specific diseases or conditions of the body, as, for instance, Formula No. 90 was recommended "for diabetes" and Formula No. 273 for sexual weakness.

In response to an advertisement for the book, appearing in the Nature's Herb Co.'s price list, the book was ordered by F. D. Clark, Denver, Colo., and was received on May 29, 1950, from Nature's Herb Co. On June 1, 1950, Mr. Clark acknowledged receipt of the book and asked the Nature's Herb Co. where he could purchase the formulas listed therein. In reply, the Nature's Herb Co., on June 8, 1950, sent Mr. Clark a price list of the formulas listed in the book. Using the Nature's Herb Co.'s order blank, Mr. Clark ordered from the company, Formula No. 90 "For Diabetes," and the order was filled by the company on June 19, 1950. On July 1, 1950, Mr. Clark ordered Formula No. 177 "For Bright's Disease" from the book and asked if the company had Formula No. 273, also mentioned in the book for sexual weakness. Formula No. 177 was shipped, but Nature's Herb Co. wrote Mr. Clark that Formula No. 273 was available only on prescription. On August 1, 1950, Mr. Clark ordered from Nature's Herb Co., Formula No. 153 "For Gonorrhea" and Formula No. 297 "For Ulcers" mentioned in the book. These were received from the company on August 12, 1950.

Another instance illustrating the pattern of the firm's business is: In September 1950, Mr. S. Katzman, New York, N. Y., ordered a copy of the firm's catalog and price list. Upon receipt, Mr. Katzman ordered certain of the herbs and a copy of the book "Herbs for Health." In response, he received a copy of the book "Herbs for Health" (Fourth Edition, 1944). Thereafter, Mr. Katzman ordered Formulas 270, 210, and 90 from the information contained in the book, and his order was filled on January 15, 1951.

Another instance illustrating the pattern of the firm's business is: In March 1950, Mrs. R. A. Ericson, New York City, ordered from the company the book, and a copy of the 4th Edition, 1944, of "Herbs for Health" was received. From the book, Mrs. Ericson ordered from the company Formula No. 147, offered in the book as "Of especial benefit in Liver and Gall-Bladder complaints," and the merchandise was received from the Nature's Herb Co. by Mr. Ericson on or about August 10, 1950.

Another illustration of the firm's pattern of business is: On May 13, 1951, Miss Helen Hyde, San Francisco, called at the Nature's Herb Co.'s store and inquired for the book "Herbs for Health." A copy was produced from beneath the counter. Upon asking whether the herbs listed in the book could be purchased in the store, Miss Hyde was assured that they could be. Miss Hyde then requested a price list of the herbs mentioned in the book and was supplied with a copy of "Price list of Formulas Listed in Dr. O. Mausert's Book 'Herbs for Health'," 5th Edition, printed in 1951.

Further, on June 1, 1951, Dr. P. S. Jorgensen called at the San Francisco store of the Nature's Herb Co. and asked for something on how to live right. A copy of the book "Herbs for Health" was produced from beneath the store's counter, and on page 58 Dr. Jorgensen found "Formula No. 3, Powder for Asthma," a mixture of 9 plant drugs. In reply to a question by Dr. Jorgensen, as to where he could purchase this formula, he was informed, "We have the remedy here." Dr. Jorgensen purchased the book and the formula.

On June 5, 1951, a contract signed by Nathan Podhurst, president of the Nature's Herb Co., and Miss Margaret Gross, acting for the company, was entered into with Mercury Press, San Francisco, Calif., for the printing of 5,000 copies of the book "Herbs for Health."

DISPOSITION: October 21, 1952. The Nature's Herb Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the drugs and books be released under bond, conditioned that the drugs be relabeled in such manner that all references to the books should be excluded from the labeling and that the books be sold and distributed and otherwise disposed of in such manner that they would not become a part of any sales or distributional campaign for the sale of crude drugs sponsored by or on behalf of the claimant or any other person or firm; further, that the drugs and books should not be sold or disposed of contrary to the provisions of the Federal Food, Drug, and Cosmetic Act, or other laws.

3893. Misbranding of Lebanon Brand herb tablets. U. S. v. 50,000 Herb Tablets, etc. (F. D. C. No. 33606. Sample No. 7627–L.)

LIBEL FILED: July 25, 1952, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about June 27, 1949, from Cleveland, Ohio.

PRODUCT: 50,000 *Lebanon Brand herb tablets* at Corry, Pa., in possession of the Lebanon Co., together with a number of leaflets entitled "Lebanon Brand Herb Tablets are More Than a Laxative."

RESULTS OF INVESTIGATION: The Lebanon Co., after receipt of the tablets, repacked them into 60-tablet packages and caused a number of the above-mentioned leaflets to be printed and associated with the tablets. Analysis disclosed that the tablets contained, among other things, strychnine and digitalis.

LABEL, IN PART: (Pkg) "Lebanon (Brand) Herb Tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for dyspepsia, diseases of the genito-urinary system, including inflammation and retention or incontinence of urine, congested or torpid liver, chronic rheumatism, impure blood, "bad liver," poisoned system, arthritis, and vertigo or dizziness. The article was not effective for such conditions.

Further misbranding, Section 502 (e) (2), the article contained digitalis and strychnine, and its label failed to reveal the presence and proportion of these ingredients.

DISPOSITION: November 21, 1952. Default decree of condemnation and destruction.

3894. Misbranding of barley cereal and honey. U. S. v. 64 Boxes, etc. (F. D. C. No. 33272. Sample Nos. 36966–L, 36967–L.)

LIBEL FILED: May 27, 1952, Southern District of New York.

ALLEGED SHIPMENT: On or about December 6, 1951, and January 25, 1952, from Paterson, N. J., and Los Angeles, Calif.

PRODUCT: 64 16-ounce boxes of *barley cereal* and 26 5-ounce jars and 18 1-pound jars of *honey* at New York, N. Y., in posession of Lust's Health Food Bakery, Inc.

RESULTS OF INVESTIGATION: The articles were shipped in bulk, and upon receipt by the consignee, they were repacked and relabeled.

LABEL, IN PART: (Box) "Lust's Old Fashion Barley Health Cereal"; (jar) "Pure Nature-Sweet Orange Blossom Honey."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading. The statements represented and suggested that the *barley cereal* was effective to make pure blood, to aid digestion, insure sleep, promote health, cure sickness, and prevent nervousness and sleeplessness, and that the *honey* was effective in building blood. The articles were not effective for such purposes. They were misbranded while held for sale after shipment in interstate commerce.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: October 2, 1952. Default decree of condemnation. The court ordered that a portion of the articles be delivered to the Food and Drug Administration and that the remainder be destroyed.

3895. Misbranding of cough syrup. U. S. v. 24 Dozen Bottles * * *. (F. D. C. No. 33463. Sample No. 8450–L.)

LIBEL FILED: July 15, 1952, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about April 16, 1952, by the Aetna Chemical Co., from Detroit, Mich.

PRODUCT: 24 dozen 8-ounce bottles of *cough syrup* at Farrell, Pa. Examination showed that the product contained 106.5 U. S. P. units of vitamin A and 7.5 U. S. P. units of vitamin D per teaspoonful. U. S. P. cod liver oil contains in each teaspoonful not less than 3,900 U. S. P. units of vitamin A and not less than 390 U. S. P. units of vitamin D.

LABEL, IN PART: "Greenstone's Cough Syrup * * * With Cod Liver Oil Concentrate."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "With Cod Liver Oil Concentrate" and the picture of a fish on the label were misleading since the product provided but a small fraction of the therapeutic dose of cod liver oil, as shown by its vitamins A and D content.

DISPOSITION: November 21, 1952. Default decree of condemnation. The court ordered that the product be delivered to a charitable institution.

3896. Misbranding of Sur-San Powder. U. S. v. 81 Kits, etc. (and 1 other seizure action). (F. D. C. No. 30922. Sample Nos. 19015–L, 19016–L.)

LIBELS FILED: April 19, 1951, District of Minnesota.

ALLEGED SHIPMENT: On or about June 19, 25, and 29, 1950, by the Sur-San Co., from Des Moines, Iowa.

PRODUCT: 81 kits, each containing a tube and bulb and 2 3-ounce bottles of *Sur-San Powder*, and 29 kits, each containing a tube and bulb and 1 3-ounce bottle of *Sur-San Powder*, at Minneapolis, Minn., together with various circulars entitled "What Is Sur-San?"

Examination showed that the article consisted essentially of boric acid and alum, with small proportions of thymol, eucalyptol, methyl salicylate, and menthol.

LABEL, IN PART: "Sur-San * * * Astringent Vaginal Deodorant Powder."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the circular were false and misleading since the article was not effective for the conditions stated and implied nor for the purposes mentioned: "Why I Should Use Sur-San! The secret to a perfect home is perfect health * * * Feminine Hygiene * * * alleviate—itching burning sensations—of the vaginal tract—thereby eliminating offensive discharge so common to most women * * * it is invaluable to the vaginal tract * * * Ladies going through the menopause * * * Younger women swear by it at their menstrual period—as it contains an ingredient which has a tendency to subdue these bearing down pains. * * * Sur-San has been known to clear up conditions in a very few treatments—which in some cases were of long standing. * * * It corrects the condition * * * Sur-San was primarily gotten out for the woman who cannot afford to go to her doctor frequently. It is a Home treatment. * * * Sur-San is also very efficacious in cases of * * * profuse bleeding caused from cuts. Apply on cut until blood coagulates before your doctor comes."

DISPOSITION: October 7, 1952. Default decrees of condemnation and destruction.

3897. Misbranding of Persulan hair ointment. U. S. v. 1 Jar, etc. (F. D. C. No. 32534. Sample No. 33691–L.)

LIBEL FILED: February 20, 1952, Northern District of Illinois.

ALLEGED SHIPMENT: On or about May 21, June 19, October 26, and December 27, 1951, and January 7, 1952, by Drake Laboratories, Inc., from Detroit, Mich.

PRODUCT: *Persulan hair ointment.* 1 1-pound jar, 2 8-ounce jars, 2 4-ounce jars, 47 2-ounce jars, and 33 ½-ounce jars; 126 sets, each containing 1 2-ounce jar and 1 ½-ounce jar; and 520 cartons, each containing 1 2-ounce jar and 5 ½-ounce jars, at Chicago, Ill., together with a leaflet headed "Pertinent Facts About Persulan" accompanying each jar, and 82 envelopes known as "Guarantee Sets" which were shipped with the product.

LABEL, IN PART: (Jar) "Persulan * * * Contains Balsam Peru, Sulphur Prec., Lanolin, Resorcinol, Jaborandi Tinct."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, on the carton labels and in the above-mentioned printed and graphic matter which accompanied the article, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for baldness, itchy scalp ringworm, scalp

disorders, and psoriasis, and that the article would give one a healthy scalp. The article was not an adequate and effective treatment for such conditions.

DISPOSITION: October 29, 1952. Drake Laboratories, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

3898. Misbranding of Holder's Condensator device, Holder's Metallic Indicator Device, and Holder's Antimet Compound tablets. U. S. v. 1 Device, etc. (F. D. C. No. 33924. Sample Nos. 14196–L, 14201–L, 14202–L.)

LIBEL FILED: October 22, 1952, District of Colorado.

ALLEGED SHIPMENT: The *Holder's Condensator device* and the *Holder's Metallic Indicator device* were shipped on or about October 24, 1949, by the Dresser Electric Co., from Detroit, Mich.; the *Holder's Antimet Compound tablets* were shipped on or about February 15, 1950, by the Redloh Distributing Co., from Detroit, Mich.; and a number of leaflets and pamphlets were shipped at various times by W. E. Holder (Holder's Research Laboratories), from Windsor, Canada.

PRODUCT: 1 *Holder's Condensator device*, 1 *Holder's Metallic Indicator device*, and 1,200 tablets of *Holder's Antimet Compound* contained in bottles at Denver, Colo., together with a number of copies of leaflets entitled "An Astounding Discovery" and "Case History Victory Over Arthritis," and a number of pamphlets entitled "In the Interest of Preventive Medicine," "Free Sciences' Challenges Health Administration," "Remarkable Results Obtained By Use of Holder's Anti-Met Tablets," "Reports and Calibration," and "Biological Attack on Disease."

The *Holder's Metallic Indicator device* was represented to be a method of determining metallic content in humans, water, milk, liquids, food, and soil. The *Holder's Condensator device* was represented as capable of producing shock therapy with intra-cellular massage. It was an ordinary spark generator whose voltage output caused a gas to glow similar to a neon sign. No examination has been made of the *Holder's Anti-Met Compound tablets* since they were assumed to have the composition stated on the label. The ingredient "Volclay" was found to be bentonite.

LABEL, IN PART: " 'Holder's' Ultra-Short Wave H. F. Condensator * * * Made in U. S. A., Holder's H. F. Condensator Co., Detroit, Michigan," " 'Holder's' Metallic Indicator * * * Holder's Research Laboratories, Windsor, Ontario, Canada," and " 'Holder's' 'Antimet' Compound Compressed Each Contains Glycerin 1.13 grs. Volclay 12.00 grs."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets and pamphlets accompanying the devices and the tablets were false and misleading. The statements represented and suggested that the devices and the tablets were capable of preventing, diagnosing, and curing almost all diseases known to man, the causes of which are due to metallic poisoning from the ingestion of chlorinated water and foods grown on commercially fertilized soils, including infantile paralysis, cancer, arthritis, stomach troubles, anemia, rheumatism, chronic respiratory infections, stomach peptic ulcers, constipation, abnormal colon (spastic colon, ulcerated colon, and atonic colon), nervousness, sclerosis, anemia, rickets, tuberculosis, syphilis, rheumatoid arthritis, heart disease, eye ailments, bad teeth, perverted appetite, digestive impairment, debility, dysmenorrhea, amenorrhea, nervous dis-

turbance, Hodgkin's disease, children's ailments, hardening of the arteries, pulmonary ailment, leukemia, dental decay, cataract, glaucoma, diseases of the eyes, deafness, head noises, diseases of the spinal nerve centers, diseases of the feet and ankles, circulatory disorders, gout, muscular rheumatism, diabetes, asthma, epilepsy, neuritis, neuralgia, sciatica, lumbago, headaches, sinus trouble, hay fever, colds, bronchitis, influenza, tonsillitis, quinsy, laryngitis, prostate trouble, and female ailments. The devices and the tablets, either alone or in combination, were not capable of preventing, diagnosing, or curing any diseases or condition, and were completely ineffective for any therapeutic use.

DISPOSITION: December 10, 1952. Default decree of condemnation. The court ordered that the devices and tablets and the leaflets and pamphlets be turned over to the Food and Drug Administration.

3899. Misbranding of colon irrigator device. U. S. v. 111 Enema Bags, etc. (F. D. C. No. 33891. Sample Nos. 37917–L, 37927–L.)

LIBEL FILED: October 2, 1952, Southern District of New York.

ALLEGED SHIPMENT: The enema bags were shipped from Providence, R. I., on or about April 2 and August 7, 1952, and the injection points and faucets for use with the bags were shipped from Hawthorne, N. J., on or about September 9, 1952.

PRODUCT: 111 enema bags, 28 injection points, and 28 faucets, together with a number of *colon irrigator devices* assembled from such parts, and booklets entitled "Why We Should Bathe Internally," at New York, N. Y., in possession of J. B. L. Cascade, Inc.

RESULTS OF INVESTIGATION: Investigation disclosed that the consignee assembled the enema bags, injection points, and faucets, and packaged them into cartons, together with a tube of a lubricant, a jar containing a scented mixture of salt, soda, and borax, and a leaflet entitled "Condensed Directions for Using the J. B. L. Cascade."

LABEL, IN PART: (Carton) "For Colon Hygiene At Home J. B. L. Cascade Internal Bath * * * Mfd. For Tyrrell's Hygienic Institute, Inc. * * * New York * * * N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the device, namely, on the carton label and in the booklet entitled "Why We Should Bathe Internally," were false and misleading. The statements represented and suggested that the device constituted an adequate and effective means of treatment and prevention for colon hygiene, auto-intoxication (intestinal toxemia), chronic constipation, continued fatigue, lassitude, general debility, unusual nervousness, feeling of being dragged down, absence of a maximum of buoyant energy which characterizes a normal healthy person, increased susceptibility to colds due to a "run down" state of health, various kinds of headaches, certain so-called "rheumatic" pains, distress after eating, some states of insomnia, gallstones, many abnormal skin conditions, "out of sorts," irritability, restlessness, inability of the blood to carry proper nourishment to the different organs of the body, diminished body resistance, various infections, poisons created by abnormal disease conditions, chronic invalidism, functional and degenerative structural changes, decreased mental and physical efficiency, mucous colitis, arthritis, many mental conditions, hypertension, coronary disease, chronic abdominal distension, colitis, aggravation of existing cardiac, renal, hepatic, digestive, and nervous condi-

tions, enteritis accompanied by much mucus, dizziness, anorexia, marked apathy, spots in front of the eyes, lowered muscular tone in the intestine with atony and constipation, irritation and spasm with diarrhea and excessive production of flake mucus diverticulosis, ulceration, visceroptosis, sluggish liver, and abnormal liver function. The device did not constitute an adequate and effective means of treatment for such symptoms, diseases, and conditions. The device was misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: October 17, 1952. J. B. L. Cascade, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond for relabeling, under the supervision of the Federal Security Agency.

3900. Misbranding of Oxydonor device. U. S. v. 7 Boxes, etc. (F. D. C. No. 33879. Sample No. 36277–L.)

LIBEL FILED: September 22, 1952, Northern District of Ohio.

ALLEGED SHIPMENT: During January 1952, by the Hydrotonic Co., from New York, N. Y.

PRODUCT: *Oxydonor device.* 7 boxes, each containing 1 device and 1 copy of a booklet entitled "Brief Directions for the Use of Oxydonor," at Cleveland, Ohio, together with a number of booklets entitled "Oxydonor No. 2 and Binora."

Examination showed that the device consisted of a hollow metal cylinder filled with an iron compound, such as iron carbonate or iron oxide, into one end of which was screwed a plug to which was attached a length of wire. The distal end of the wire was attached to a metal disc, to which was attached also an elastic tape by means of which the disc could be held against the user's body.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklets were false and misleading. The statements represented and suggested that the device would act effectively to cure all forms of disease, including nervous prostration, Bright's disease, rheumatism (sciatic, muscular, inflammatory), stomach trouble, catarrh, indigestion, dysentery, lung trouble, erysipelas, diphtheria, bronchitis, dropsy, ulcers, tumors, abscesses, spinal disease, blood poison, liver, kidney, and bladder disease, all fevers, pneumonia, la grippe, colds, headaches, appendicitis, paralysis, and diseases of women and children. The device would not act effectively against such diseases. The article was misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: November 25, 1952. Default decree of condemnation and destruction.

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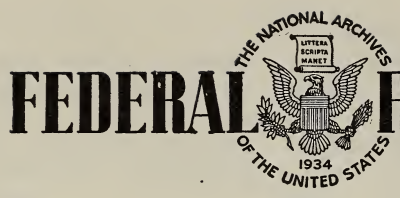
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[1] (3885) Seizure contested. Contains order of the court.

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[1] (3885) Seizure contested. Contains order of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1953



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D. D. N. J., F. D. C. 3901–3920

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Issued July 1953

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3901–3920

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *July 1, 1953.*

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DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3901. Misbranding of sulfadiazine tablets, Nembutal Sodium capsules, Tuinal capsules, diethylstilbestrol perles, and Dexedrine Sulfate tablets. U. S. v. Henry R. Namour and John C. Wicks. Pleas of nolo contendere. Imposition of sentence suspended and defendants placed on probation for 1 year. (F. D. C. No. 30025. Sample Nos. 76416–K, 76417–K, 77107–K to 77109–K, incl., 77112–K, 77131–K, 77132–K.)

INFORMATION FILED: September 11, 1951, Eastern District of Arkansas, against Henry R. Namour, a partner in the partnership trading as Henry's Drug Store, Helena, Ark., and John C. Wicks, pharmacist for the firm.

INTERSTATE SHIPMENT: From the States of Missouri, Tennessee, Indiana, and Pennsylvania, into the State of Arkansas, of quantities of *sulfadiazine tablets*, *Nembutal Sodium capsules*, *Tuinal capsules*, *diethylstilbestrol perles*, and *Dexedrine Sulfate tablets*.

ALLEGED VIOLATION: On or about March 7, 8, and 9, 1950, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

John C. Wicks was charged with the violations involved in the first 5 counts of the information, and Henry R. Namour was charged with the violations involved in the remaining 3 counts.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs bore no labels containing accurate statements of the quantity of the contents and, with the exception of 1 lot of *Tuinal capsules* and the *diethylstilbestrol perles*, failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the *Nembutal Sodium capsules* and the *Tuinal capsules* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *Dexedrine Sulfate tablets* bore no label containing the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: September 18, 1951. Pleas of nolo contendere having been entered, the court suspended the imposition of sentence and placed the defendants on probation for 1 year.

3902. Misbranding of Pabst Okay Special. U. S. v. 33 Bottles * * *. (F. D. C. No. 34094. Sample No. 35968–L.)

LIBEL FILED: November 3, 1952, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 26, 1952, by Myers Laboratories, Inc., from Warren, Pa.

PRODUCT: 33 bottles of *Pabst Okay Special* at Cleveland, Ohio. Examination disclosed that the product was a dark green liquid with a bitter and somewhat burning taste and that it consisted essentially of plant extractives, chloroform, alcohol, and volatile oils.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the circular enclosed in the retail carton, represented and suggested that when the article was taken in conjunction with the diet recommended in the circular and with other treatments recommended therein, the article was an adequate and effective treatment for gonorrhea, which representations and suggestions were false and misleading since the article, either alone or when taken in conjunction with the recommended diet and other treatments recommended, was not an adequate and effective treatment for gonorrhea.

Further misbranding, Section 502 (a), the labeling of the article represented and suggested also that the article would reduce the discharge of pus due to gonorrhea and other venereal diseases, which representations and suggestions were false and misleading since the article was not effective in the reduction of the discharge of pus due to gonorrhea or other venereal diseases; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which the article was intended.

DISPOSITION: December 15, 1952. Default decree of condemnation and destruction.

3903. Misbranding of Cystex, Romind, and Mendaco. U. S. v. 48 Dozen Packages, etc. (F. D. C. No. 33257. Sample Nos. 13847–L to 13849–L, incl.)

LIBEL FILED: June 3, 1952, District of Colorado.

ALLEGED SHIPMENT: On or about November 10 and December 5 and 28, 1951, and January 17, February 5 and 23, and April 3 and 30, 1952, by the Knox Co., from Newark, N. J.

PRODUCT: 48 dozen $1.00-size packages and 24 dozen $2.00-size packages of *Cystex*, 33 dozen $1.00-size packages and 13 dozen $2.00-size packages of *Romind*, and 19 dozen $0.75-size packages, 36 dozen $1.25-size packages, and 18 dozen $2.50-size packages of *Mendaco*, at Denver, Colo.

RESULTS OF INVESTIGATION: On March 30 and April 13, 1952, in editions of the local newspaper, there appeared advertisements for *Cystex* placed by an advertising agency for and on behalf of the Knox Co.

LABEL, IN PART: "Cystex * * * Each Tablet contains Acetophenetidin 1½ grains, Methenamine and Benzoic Acid."

NATURE OF CHARGE: *Cystex.* Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article was not capable of fulfilling the promises of benefit made for it: (Carton) "Usually gives splendid palliative relief in acid urine for minor discomfort and irritation due to temporary non-organic and non-systemic Kidney and Bladder disturbances," (carton and leaflet entitled "Directions for Use" enclosed in carton) "Directions for use * * * In responsive cases discontinue when not needed for relief * * * Take Cystex long enough for a fair trial, and keep it on hand for quick use if needed again," (leaflet entitled "Directions for Use" enclosed in carton) "Take New Improved Cystex with utmost confidence. It is tried and true," and (leaflet entitled "A letter to you from our president" enclosed in carton) "Knox products * * * usually give very satisfactory results * * * try Knox Products, which your family may require, with the realization that they have proven highly satis-

factory to the majority of the millions of people who have used them." The article was misbranded in the above respect when introduced into and while in interstate commerce. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use to "whip" backache; to curb loss of sleep; for nagging, bearing down backache, cloudy, offensive, or burning urine, bladder weakness (getting up nights or frequent day passages), nervousness, headaches, leg pains, and loss of pep due to simple kidney and bladder troubles without organic or systemic cause; to enable the user to feel better and overcome a tired, achy feeling after colds, nervous tension, depression, tiredness on arising, roving aches and pains in muscles and joints; to supply internal refreshment; to bring greater pep, happiness, and earning power; to overcome pains in the groin, hips, and lower abdomen, and a feeling of pressure or fullness in the bladder; to cleanse the body internally and overcome nearly all kinds of aches and pains; to enable the user to relax better, get more refreshing sleep, gain pep, happiness, and the vital energy necessary to enjoy life; to enable the user to wake up full of pep, rarin' to go; to aid nature in stimulating an increase of energy, which may help one feel years younger; and to relieve suffering, which were the conditions for which the article was intended. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

Romind and *Mendaco*. Misbranding, Section 502 (a), the labeling of the *Romind*, namely, a leaflet entitled "For Your Family Medicine Chest" which was enclosed with the article, and the labeling of the *Mendaco*, namely, a leaflet entitled "A letter to you from our president" which was enclosed with this article, contained statements relating to the drug known as *Cystex*, which statements were false and misleading since *Cystex* was not capable of fulfilling the promises of benefit made for it. The statements represented and suggested that *Cystex* would help the kidneys remove excess urinary acids, palliate burning and smarting of the urinary passages and bladder irritation, and help the kidneys flush out waste which may become troublesome if allowed to accumulate; that *Cystex* would aid nature in stimulating an increase of energy, which may easily help one feel years younger; and that *Cystex* would be effective in the treatment of headaches, nervousness, rheumatic pains, loss of pep, backache, leg pains, cloudy, offensive, or burning urine, and bladder weakness. The *Romind* and *Mendaco* were misbranded in this respect when introduced into and while in interstate commerce.

DISPOSITION: September 26, 1952. Default decree of condemnation and destruction.

3904. Misbranding of Special Formula tablets and Miller's Compound tablets. U. S. v. 1 drum, etc. (F. D. C. No. 31642. Sample No. 3396–L.)

LIBEL FILED: On or about September 19, 1951, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about April 20, 1951, by the National Drug Co., from Philadelphia, Pa.

PRODUCT: 1 drum containing 35,000 *Special Formula tablets*, and 10 bottles, each containing 50 tablets, of *Miller's Compound tablets*, at Richmond, Va., in the possession of T. A. Miller Co., Inc., together with a number of loose bottle labels.

RESULTS OF INVESTIGATION: The tablets in the bottles had been repackaged, by the consignee, from drums of *Special Formula tablets* included in the above-mentioned shipment.

LABEL, IN PART: (Drum) "Special Formula No. A–2343 Rx Compressed Tablets Resorcin 1 gr. Powd. Rhubarb Equiv. 2 grs. Sodium Sulfate Dried 2 grs. Bismuth Subsalicylate 2 grs." and (bottle) "Tablets Miller's Compound Resorcin Bismuth and Rhubarb Tablets (An Antacid and Mild Laxative). Active Ingredients: Resorcin, Bismuth Subsalicylate, Sodium Sulphate, Rhubarb."

NATURE OF CHARGE: Misbranding (tablets in drum and bottles), Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use. The article was misbranded in this respect when introduced into and while in interstate commerce.

Misbranding (tablets in bottles), Section 502 (a), the label statements "(An antacid and Mild Laxative) Active Ingredients: Resorcin * * * Sodium Sulphate, Rhubarb. * * * For Indigestion * * * As a Laxative in Constipation * * * To avoid dependence on laxatives take only when needed" were false and misleading since resorcin, sodium sulfate and rhubarb would contribute nothing to the antacid effects of the product; the article was not an adequate and effective treatment for all types of indigestion; and it was not a laxative; and the label statement "Active Ingredients: Resorcin, Bismuth Subsalicylate, Sodium Sulphate, Rhubarb" was false and misleading since bismuth subsalicylate was the sole active ingredient of the article. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use as an antacid. The article was misbranded in these respects while held for sale after shipment in interstate commerce.

DISPOSITION: September 9, 1952. Default decree of condemnation and destruction.

3905. Adulteration and misbranding of Supra-Vite Special and Supra-Vite Junior. U. S. v. 80 Cases, etc. (F. D. C. No. 33519. Sample Nos. 27293–L to 27295–L, incl.)

LIBEL FILED: August 26, 1952, Northern District of California.

ALLEGED SHIPMENT: Between the approximate dates of February 6, 1952, and August 17, 1952, by the Supra-Vite Corp., from New York, N. Y.

PRODUCT: 80 cases, each containing 24 cartons, of *Supra-Vite Special* (capsules and tablets), 35 cases, each containing 24 cartons, of *Supra-Vite Junior* (capsules and tablets), and 60 cases, each containing 12 cartons, of *Supra-Vite Junior* (powder), at San Francisco, Calif., and Modesto, Calif., together with printed matter entitled "Supra-Vite Sales Manual," a leaflet "Supra-Vite Life is Worth Living," a book by D. T. Quigley "The National Malnutrition," a pamphlet "Your Most Priceless Possession," a leaflet by Fred Bailey (American Magazine, October 1947) "We Feed Our Hogs Better Than Our Children," "Modern Miracle Men" by Rex Beach, "Why We Need Vitamin E" by August J. Pacini, "Soil, a Foundation of Health," by Arnold Yerkes (International Harvester Co., 1946), "—For Heart Disease: Vitamin E" by J. D. Ratcliff (Coronet, October 1948), a leaflet "Why Are We in America Suffering from Malnutrition That Threatens to Make Us a 4–F Nation?" and a leaflet "Malnutrition The Hidden Hunger Menace."

LABEL, IN PART: "Supra Vite Special An Improved Highly-Concentrated Food Supplement * * * Four red vitamin capsules and four mineral tablets (suggested daily intake) supply the following amounts and proportions of the minimum adult daily requirements. Vitamin A . . . 25,000 USP units . . . 624% Vitamin D . . . 2,000 USP Units . . . 500% Vitamin B_1 . . . 10 Mgs.

. . . 1000% Vitamin B_2 . . ..10 Mgs. . . . 500% Vitamin B_6 . . . 2 Mgs. Vitamin B_{12} . . . 0.5 Mcg. Vitamin C . . . 300 Mgs. . . . 1000% Calcium Pantothenate . . . 20 Mgs. Choline Dihydrogen Citrate . . . 10 Mgs. Niacinamide . . . 100 Mgs. Vitamin E . . . 100 Mgs. (100 int. Units) Calcium . . . 750 Mgs. . . . 100% Phosphorus . . . 380 Mgs. . . . 50% Iron . . . 10 Mgs. . . . 100% Iodine . . . 0.2 Mg. . . . 200% Copper . . . 0.1 Mg. Fluorine . . . 0.2 Mg. Manganese . . . 1 Mg. Cobalt . . . 0.1 Mg. Nickel . . . 0.1 Mg. Zinc . . . 0.1 Mg. Chlorophyll . . . 1 Mg. Kelp . . . 6 Grs. Folic Acid . . . 1 Mg. Rutin . . . 1 Mg. Inositol . . . 15 Mgs. Para-Amino Benzoic Acid . . . 15 Mgs." and "Supra Vite Junior A Concentrated Food Supplement In Powder Form * * * Two level teaspoonfuls (10 gms. suggested daily intake) [or "Supra Vite Junior A Concentrated Food Supplement * * * Two red vitamin capsules, one yellow Vitamin E perle and four mineral tablets (suggested daily intake)] supply the following amounts and proportions of the minimum adult daily requirements: Vitamin A . . . 20,000 USP Units . . . 500% Vitamin D . . . 2,000 USP Units . . . 500% Vitamin B_1 . . . 10 Mgs. . . . 1000% Vitamin B_2 . . . 6 Mgs. . . . 300% Vitamin B_1 . . . 2 Mgs. Vitamin B_{12} . . . 0.5 Mcg. Vitamin C . . . 200 Mgs. . . . 666% Calcium Pantothenate . . . 10 Mgs. Choline Dihydrogen citrate . . . 10 Mgs. Niacinamide . . . 50 Mgs. Vitamin E . . . 5 Mgs. (5 Int. Units) Calcium . . . 750 Mgs. . . . 100% Phosphorus . . . 380 Mgs. . . . 50% Iron . . . 10 Mgs. . . . 100% Iodine . . . 0.2 Mg. . . . 200% Copper . . . 0.1 Mg. Cobalt . . . 0.1 Mg. Manganese . . . 1 Mg. Zinc . . . 0.1 Mg. Chlorophyll . . . 1 Mg. Nickel . . . 0.1 Mg. Inositol . . . 15 Mgs. Para-Amino Benzoic Acid . . . 15 Mgs."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the *Supra-Vite Special* and the *Supra-Vite Junior* (capsules and tablets) differed from that which they purported and were represented to possess. The labels of the *Supra-Vite Special* declared that 4 red vitamin capsules and 4 mineral tablets of the articles would supply 380 milligrams of phosphorus, whereas the capsules and tablets would supply a lesser amount of phosphorus. The label of the *Supra-Vite Junior* (capsules and tablets) declared that 2 red vitamin capsules, 1 yellow vitamin E perle, and 4 mineral tablets of the articles would supply 750 milligrams of calcium and 380 milligrams of phosphorus, whereas such capsules, perle, and tablets would supply lesser amounts of calcium and phosphorus.

Misbranding, Section 502 (a), the labeling of the articles, when taken as a whole, as well as through specific claims, and in the setting in which the labeling was presented, contained statements which represented and suggested that (a) almost everyone in the United States is either ill or about to become ill as a result of various deficiency ailments; (b) our health is being undermined by malnutrition and/or dietary deficiencies which cause all illnesses except those due to accident, poison, infection, and exposure; (c) the average American diet is deficient in vital food factors, resulting in malnutrition; (d) these dietary deficiencies are attributable to depleted soil, processing practices, and storage and cooking methods, which make it impossible to obtain in the diet the food factors that are essential to health; and (e) the only way to achieve and maintain health in the United States today, in short, to cure, prevent, and treat all diseases and the ailments afflicting mankind, is to use a vitamin and mineral supplement, namely "Supra-Vite," which representations and suggestions were false and misleading since they are contrary to fact.

Further misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading. The statements represented and suggested that the articles were an adequate and effective treatment for all diseases or ill health (except from accident, poison, exposure, or bad habits), e. g., diabetes, impaired visual function, poor posture, flat feet, skin eruptions, sore throats, spinal curvature, allergies, heart disease, arthritis, sterility, nerve and muscle disorders, as well as other major disorders, general conditions such as a lack of good health, and personality disorders; and that the articles were effective to provide buoyant health and a super state of well-being. The articles were not an adequate and effective treatment for such conditions and purposes.

Further misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in the treatment of all diseases or ill health, e. g., diabetes, impaired visual function, poor posture, flat feet, skin eruptions, sore throats, spinal curvature, allergies, heart disease, arthritis, sterility, nerve and muscle disorders, as well as other major disorders, general conditions such as a lack of good health and personality disorders, and for the provision of buoyant health and a super state of well-being, which were the conditions for which the articles were intended.

The articles were adulterated and misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: October 17, 1952. The Supra-Vite Corp., claimant, having consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the labeling of the products, consisting of the accompanying literature, be destroyed and that the products without such labeling be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency.

3906. Misbranding of Hope mineral tablets. U. S. v. 140 Bottles * * * (and 17 other seizure actions). (F. D. C. Nos. 32479, 33013, 33016, 33028, 33159 to 33162, incl., 33164, 33166 to 33169, incl., 33173 to 33175, incl., 33177, 33183, 33198. Sample Nos. 6407–L to 6410–L, incl., 7040–L, 7042–L, 7043–L, 7903–L, 7904–L, 24077–L, 25818–L, 27220–L, 27450–L, 27462–L, 29206–L to 29209–L, incl., 29212–L, 29213–L, 29216–L, 31609–L, 35289–L.)

LIBELS FILED: Between February 1 and May 14, 1952, Western District of Wisconsin, Western District of Pennsylvania, Northern District of California, Eastern District of Illinois, District of Oregon, District of Massachusetts, and District of New Jersey.

ALLEGED SHIPMENT: Between December 12, 1951, and April 19, 1952, by the Hope Co., from St. Louis, Mo., and East St. Louis, Ill.

PRODUCT: 7,294 40-tablet bottles of *Hope mineral tablets* at Monroe, Wis.; New Kensington, Brownsville, Uniontown, and Ellwood City, Pa.; Richmond, Santa Cruz, and Petaluma, Calif.; Effingham, Ill.; Portland, Oreg.; Boston, Mass.; and Vineland and Elizabeth, N. J.

RESULTS OF INVESTIGATION: Various representations concerning the conditions for which the product was intended were published in advertisements contained in local newspapers at the places where the product was located. These advertisements were printed on instructions of, and from mats furnished by, the Hope Co.

LABEL, IN PART: "Hope Mineral Tablets with B-Vitamins Dietary Supplement Each tablet contains 20 mgm. Iron; ½ mgm. Vitamin B_1; 1 mgm. Vitamin B_2; and 5 mgm. Niacin. Also contains traces of other minerals (elements) extracted from a natural clay" or "Hope Mineral Tablets Dietary Supplement Each tablet contains 20 mgm. of iron. Also contains traces of other minerals (extracted from a natural clay) plus ½ mgm. Vitamin B_1, 1 mgm. Vitamin B_2, and 5 mgm. Niacin." (Some of the labels declared also "½ mcg. Vitamin B_{12}.")

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of arthritis, stomach ailments, neuritis, dizzy spells, nervousness, bloating, rheumatism, headaches, weak kidneys, lack of vitality, weak back, acids, toxins, aching back, lumbago, sleepless nights, bad breath, bad complexion, decaying teeth, failing eyesight, lack of energy, underweight, irritability, frequent risings at night, lack of appetite, leg pains, digestive disturbances, vague pains, weakness, heartburn, numbness, paleness, stomach gas, listlessness, tiredness, powers weakened, general rundown feeling, weak sexual powers, and lack of ambition and sparkle, which were the conditions for which the article was intended. The article was misbranded in this respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the labeling of the portion of the article at Monroe, Wis., and Richmond, Calif., namely, clippings which were from local newspapers and which accompanied the article, was false and misleading. The labeling contained statements which represented and suggested that the article was an adequate and effective treatment for arthritis, stomach ailments, neuritis, rheumatism, headaches, weak kidneys, dizzy spells, nervousness, bloating, acids, toxins, lack of vitality and energy, aching back, lumbago, underweight, lack of ambition and sparkle, powers weakened, digestive disturbances, vague pains, bad breath, weakness, heartburn, numbness, paleness, stomach gas, tiredness, listlessness, and irritability. The article was not an adequate and effective treatment for such conditions. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

The portion of the article at Monroe, Wis., consisting of a lot of 140 bottles, was alleged to be misbranded also under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: Between March 6 and September 5, 1952. Default decrees of condemnation. The courts ordered that the Wisconsin and Pennsylvania lots of the product be delivered to local hospitals and that the other lots of the product be destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3907. Adulteration of dl-desoxyephedrine hydrochloride tablets. U. S. v. 1 drum, etc. (F. D. C. No. 32981. Sample No. 13009–L.)

LIBEL FILED: April 30, 1952, Northern District of Texas.

ALLEGED SHIPMENT: On or about May 8, 1951, by the Keith-Victor Pharmacal Co., from St. Louis, Mo.

*See also No. 3905.

PRODUCT: 1 drum of *dl-desoxyephedrine hydrochloride tablets*, together with a number of bottles containing tablets which had been removed from the drum and repacked at Big Spring, Tex.

Examination showed that the product contained no dl-desoxyephedrine hydrochloride or dextro-N-methyl amphetamine hydrochloride but did contain approximately 5 milligrams of dextro-amphetamine hydrochloride per tablet.

RESULTS OF INVESTIGATION: The tablets had been removed from the drum and repacked into the bottles by the Southern Pharmacal Co. (Leonards Rx Pharmacy), Big Spring, Tex.

LABEL, IN PART: (Drum) "Lot No. 8986 Count 100,000 Date 5–3–51 Compressed Tablets dl-Desoxyephedrine Hydrochloride 5 Mg." (bottle) "5 mg. Dextro-N-Methyl Amphetamine Hcl. Each tablet contains . . . 5 mg."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), dextro-amphetamine hydrochloride had been substituted for dl-desoxyephedrine hydrochloride in the drum and dextro-N-methyl amphetamine hydrochloride had been substituted for dl-desoxyephedrine hydrochloride in the bottles. The article was adulterated when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: July 16, 1952. Default decree of condemnation. The court ordered that the product be delivered to a Government hospital for its use.

3908. Adulteration and misbranding of Livo B–12 injection. U. S. v. 41 Bottles * * *. (F. D. C. No. 33602. Sample No. 27210–L.)

LIBEL FILED: July 31, 1952, Northern District of California.

ALLEGED SHIPMENT: On or about May 5, 1952, by the Central Pharmacal Co., from Seymour, Ind.

PRODUCT: 41 bottles of *Livo B–12 injection* at Palo Alto, Calif. Analysis showed that the article contained 33 percent of the declared amount of vitamin B_{12}.

LABEL, IN PART: (Bottle) "10 CC Vial * * * Livo B–12."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Each CC Contains * * * Vitamin B–12 50 MG."

Misbranding, Section 502 (a), the label statement "Each CC Contains * * * Vitamin B–12 50 MG" was false and misleading as applied to the article, which contained less than the declared amount of vitamin B_{12}; and the label statement "Liver Injection 10 U. S. P. Units" was false and misleading since no U. S. P. units of liver injection is recognized in the United States Pharmacopeia.

DISPOSITION: On October 8, 1952, a default decree of condemnation was entered, and the court ordered that the product be destroyed. On October 16, 1952, the decree was amended to provide for the delivery of the product to the Food and Drug Administration.

3909. Adulteration and misbranding of liver-folic acid—B_{12} injection. U. S. v. 7 Vials * * *. (F. D. C. No. 33505. Sample No. 6469–L.)

LIBEL FILED: August 1, 1952, District of Massachusetts.

ALLEGED SHIPMENT: On or about June 16, 1952, by the Addison Laboratories, from Philadelphia, Pa.

PRODUCT: 7 vials of *liver-folic acid—B_{12} injection* at Springfield, Mass. Analysis showed that the product contained less than 7 percent of the declared amount of vitamin B_{12}.

LABEL, IN PART: (Vial) "10 cc Multiple-Dose Vial Liver-Folic Acid B–12 H. P. Hematopoietic Formula For Treatment of Anemias * * * Each cc. contains: Vit. B–12 (Crystalline) 60 mcg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Each cc. contains: Vit. B–12 * * * 60 mcg."

Misbranding, Section 502 (a), the label statement "Each cc. contains: Vit. B–12 * * * 60 mcg." was false and misleading as applied to the article, which contained less than the declared amount of vitamin B_{12}.

DISPOSITION: November 10, 1952. Default decree of condemnation and destruction.

3910. Adulteration and misbranding of Nemaron capsules. U. S. v. 3 Buckets, etc. (F. D. C. No. 33339. Sample No. 46270–L.)

LIBEL FILED: July 9, 1952, Northern District of Alabama.

ALLEGED SHIPMENT: On or about February 4, 1952, by the Keith-Victor Pharmacal Co., from St. Louis, Mo.

PRODUCT: *Nemaron capsules.* 3 buckets, each containing 2,000 capsules and 26 bottles, each containing 25 capsules, 6 bottles, each containing 500 capsules, and 110 bottles, each containing 100 capsules, at Birmingham, Ala.

The capsules had been shipped in a bulk container, and were repackaged and relabeled by the consignee. Analysis showed that the product contained 60 percent of the declared amount of vitamin B_{12}.

LABEL, IN PART: (Bulk container) "Each Capsule Contains Vitamin B–12 . . . . . 25 Mcgs." and (buckets and bottles) "Nemaron A Therapeutic Potency Vitamin B–12 * * * Each Capsule Contains Vitamin B–12 . . . . . 20 Mcgs."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Each Capsule Contains Vitamin B–12 . . . . . 25 Mcgs."

Misbranding, Section 502 (a), the label statement "Each Capsule Contains Vitamin B–12 . . . . . 25 Mcgs." was false and misleading as applied to the product, which contained less than the declared amount of vitamin B_{12}.

DISPOSITION: December 22, 1952. Default decree of condemnation and destruction.

3911. Adulteration and misbranding of Enca Cream. U. S. v. 23 Gross Jars, etc. (F. D. C. No. 27212. Sample Nos. 46583–K, 46584–K.)

LIBEL FILED: May 13, 1949, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 24, 1948, and April 8, 1949, by Atlas Laboratories, Inc., from Akron, Ohio.

PRODUCT: 23 gross jars of *Enca Cream*, together with a number of booklets entitled "presenting New Facts about Acne and its associated Skin Blemishes," and a number of counter display cards and window streamers, at Pittsburgh, Pa.

LABEL, IN PART: (Jar) "Active Ingredients: Tyrothricin, resorcin, zinc oxide, petrolatum Distributed by Morton Products, Inc. Cleveland 14, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since it possessed no antiseptic properties against *Staphylococcus aureus* or *Staphylococcus pyogenes* micro-organisms commonly associated with skin infections, as stated and implied in the labeling.

Misbranding, Section 502 (a), certain statements on some of the cartons containing the jars of the article, in a booklet enclosed in some of the cartons, on the above-mentioned window streamers and display cards, and in a booklet accompanying the article were false and misleading. The statements represented and suggested that the article would be effective in the treatment of pimples, blackheads, and other externally caused minor skin blemishes, burning, itching skin, and acne and its associated skin blemishes. The article would not be effective in the treatment of the conditions stated and implied.

Further misbranding, Section 502 (a), the statements "Base for the new 'wonder formula' * * * non-greasy vehicle," "Enca's greaseless cream base," and "Enca is greaseless" appearing in the above-mentioned booklet accompanying the article were false and misleading as applied to an article which contained petrolatum, a grease; and certain other statements in the above-mentioned booklet were false and misleading since they represented and suggested that the article had antiseptic properties against organisms commonly found in skin infections, whereas the article possessed no antiseptic properties against *Staphylococcus aureus* or *Staphylococcus pyogenes* micro-organisms commonly associated with skin infections.

DISPOSITION: On July 1, 1949, the manufacturer of the product, Morton Products, Inc., Cleveland, Ohio, having petitioned for the removal of the libel action for trial in the Northern District of Ohio, the United States Court for the Western District of Pennsylvania entered an order providing for such removal. Following the removal, a motion to remand the case to the court of original jurisdiction was filed, on behalf of the Government, with the United States District Court for the Northern District of Ohio. On October 25, 1949, the court handed down the following decision providing for the remanding of the case:

JONES, *District Judge:* "This is a libel brought under favor of 21 U. S. C. A. Sec. 334 (Pure Food and Drug Act) for the condemnation of the product and advertising matter in the caption of this memorandum. Originally the action was commenced in the Western District of Pennsylvania. Morton Products, Inc., whose principal place of business is in this division, intervened as claimant of the goods and petitioned that Court to remove this action to this district. The Court allowed the motion and the action was transferred here. The Government objected at all times to the removal and now has filed a motion to remand the action to the court of original jurisdiction.

"Apparently this action was removed to this district under favor of Section 1404 Title 28 U. S. C. A. If that section applies, the action was properly transferred and the Government's motion must be overruled.

"The pertinent part of 1404 (a) is as follows: '* * * A district court may transfer any civil action to any other district where it might have been brought.'

"It is true that under Supreme Court decisions this action would be covered by the phrase 'any civil action,' but, by the clear and unambiguous words of the statute, such civil action cannot be transferred to a district where the action could not originally have been started.

"This libel having been brought under favor of 21 U. S. C. A. 334, the articles may be condemned 'In any district court of the United States within the jurisdiction of which the article is found.' Since the articles were found in the Western District of Pennsylvania this action only could be commenced in that district. It could not, under Section 334, have been brought in this

district. Since this is so and since Section 1404 (a) may only be used to transfer actions to districts where they could have been brought, it follows that Section 1404 (a) could not be used to transfer this action here.

"It should also be noted that Section 1404 (b) provides for transfer of *in rem* actions. However, the revisers' notes show that this section 1404 (b), was meant to apply only to removal of causes between divisions within districts and not to removal of actions between districts. Section 1404 (b), therefore, can have no application to this action.

"Since Section 1404 (a) does not apply, the special venue section of 21 U. S. C. A. does. This section allows removal in this type action to district courts 'of reasonable proximity to claimant's place of business.' This phrase has been interpreted to exclude the district or division in which claimant's principal place of business is found. (U. S. v. 600 Units . . . . ., 60 F. Supp. 144; U. S. v. Six Dozen Bottles . . . . . Dr. Peter Kurik, 55 F. Supp. 458; U. S. v. 26 Dozen Bottles . . . . . Cervigards, 60 F. Supp. 626.) As this district is the claimant's principal place of business, it follows that this action has been removed to a district which has not been given authority under Section 334 to try the action.

"Claimant contends that even if this action is not properly here, that the Court cannot re-examine the order of the District Court of the Western District of Pennsylvania. The only case it cites, however, is one where the court, to which the action was removed over protest of defendant, had proper venue and jurisdiction to hear the action. In this cause, Section 334 does not permit this Court to hear the action. In U. S. v. 26 Dozen Bottles . . . . . of Cervigards, 60 F. Supp. 626, the Court to which the action was improperly removed, remanded the action to the Court of original jurisdiction. There is adequate authority for remanding an action when it has been improperly transferred under 21 U. S. C. A. 334.

"This action will be remanded to the court of original jurisdiction."

An appeal from the above court decision was taken by the manufacturer to the United States Court of Appeals for the Sixth Circuit, and on May 31, 1950, the appeal was dismissed pursuant to the motion of the manufacturer.

The case was returned to the United States District Court for the Western District of Pennsylvania, and, on January 23, 1953, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3912. Action to enjoin and restrain the interstate shipment of misbranded Dunkler Cancer Test Reagens. U. S. v. William Dunkler (William Dunkler Laboratories). Consent decree granting permanent injunction. (Inj. No. 255.)

COMPLAINT FILED: October 29, 1952, Northern District of Illinois, against William Dunkler, trading as the William Dunkler Laboratories, Chicago, Ill.

NATURE OF CHARGE: That the defendant had been and was at the time manufacturing, preparing, packing, distributing, and selling drugs intended for use in the diagnosis of cancer and labeled, in part, "Dunkler Cancer Test Reagens I" and "Dunkler Cancer Test Reagens II"; that he had been and was at the time introducing and delivering, and causing the introduction and delivery, for introduction of the drugs into interstate commerce; and that the drugs were misbranded as follows:

Section 502 (a), the labelings contained statements which represented and suggested that the drugs constituted a reliable means of diagnosing cancer, which statements were false and misleading since they did not constitute a

*See also Nos. 3902–3906, 3908–3911.

reliable means of diagnosing cancer; Sections 502 (b) (1) and (2), the drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and, Section 502 (e) (1), the label of the "Dunkler Cancer Test Reagens II" failed to bear the common or usual name of the drug, ether.

The complaint alleged further that the continued introduction and delivery of the drugs into interstate commerce was dangerous to the public and could cause irreparable injury through failure to diagnose a cancerous condition, which failure might well lead to such delay in obtaining treatment that irreparable injury would occur; and that it was necessary that a temporary restraining order issue ex parte, pending hearing for a preliminary injunction.

The complaint prayed that the court grant a temporary restraining order restraining the defendant, his agents, servants, employees, representatives, and all persons in active concert or participation with him from directly or indirectly introducing or delivering the drug for introduction into interstate commerce; that an order be entered directing the defendant to show cause why the relief prayed for should not be granted; that upon the hearing of such order, a preliminary injunction be granted; and that after further due proceedings, such preliminary injunction be made permanent.

DISPOSITION: On October 30, 1952, the court issued a temporary restraining order, and on November 17, 1952, the defendant having consented to the entry of a decree, judgment was entered that the defendant be perpetually enjoined and restrained from directly or indirectly introducing or causing the introduction or delivery into interstate commerce of articles of drugs misbranded within the meaning of Section 502.

3913. Misbranding of calcium pantothenate tablets. U. S. v. 14 Bottles * * *. (F. D. C. No. 26950. Sample No. 48288–K.)

LIBEL FILED: March 25, 1949, District of Delaware.

ALLEGED SHIPMENT: On or about September 24, 1948, from Newark, N. J.

PRODUCT: *Calcium pantothenate tablets.* 14 bottles, each containing 100 tablets, in the possession of the Natural Food Centre, Wilmington, Del. The product was shipped in bulk containers, and was bottled and labeled by the consignee, the Natural Food Centre.

LABEL, IN PART: (Bottle) "Daland's Calcium Panto-Thenate Tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement appearing on the bottle label "Clinical experiments have shown darkening of the hair in some cases in 1 month, others in 23 months to a year" was false and misleading since it represented and suggested that the article was effective to restore the original color to gray hair, whereas it was not effective for such purpose. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: November 27, 1951. Judson D. Ryon, claimant, trading as the Natural Food Centre, having admitted the allegations of the libel and consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

3914. Misbranding of lecithin. U. S. v. 14 Drums, etc. (F. D. C. No. 33301. Sample Nos. 37644–L, 37645–L.)

LIBEL FILED: June 23, 1952, Southern District of New York.

ALLEGED SHIPMENT: On or about April 21 and May 8, 1952, from Cleveland, Ohio.

PRODUCT: 14 drums, each containing 35 pounds, and 1 drum, containing 20 pounds, of *lecithin*, together with 1 drum, containing 20 pounds, and 248 bottles, each containing 8 ounces, of *lecithin* to which 2 percent of calcium phosphate had been added, and a number of leaflets entitled "Lecithin," at New York, N. Y., in the possession of Amend Drug & Chemical Co., Inc.

RESULTS OF INVESTIGATION: The consignee added 2 percent of calcium phosphate to the *lecithin* and bottled it in the 8-ounce bottles. The labels for the bottles and the above-mentioned leaflets were printed and used by the consignee in marketing the product.

LABEL, IN PART: (Bottle) "Lecithin * * * Contains 2% Calcium Phosphate, tribasic, N. F."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in the above-mentioned leaflet accompanying the article were false and misleading. The statements represented and suggested that the article was an effective treatment for arthritis, arteriosclerosis, coronary thrombosis, high blood pressure, low blood pressure, diabetes, many body infirmities, and a variety of other ills. The article was not an effective treatment for such conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: November 19, 1952. Amend Drug & Chemical Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

3915. Misbranding of mineral tablets and nutritional tablets. U. S. v. 390 bottles, etc. (F. D. C. No. 31635. Sample Nos. 31708–L to 31711–L, incl.)

LIBEL FILED: August 29, 1951, Southern District of Illinois.

ALLEGED SHIPMENT: On or about January 17 and June 4, 1951, by Ira Allison, M. D., from Springfield, Mo.

PRODUCT: 390 60-tablet bottles of *mineral tablets* and 570 30-tablet bottles of *nutritional tablets* at Congerville, Ill., in the possession of the Schrock Bros. Co., together with a number of leaflets entitled "Brucella Infections," "Brucellosis and Mastitis," "Summary of 'Dr. Allison Clinic' April 10, 1950," and "Review of 'Dr. Allison Clinic' March 26, 27th."

RESULTS OF INVESTIGATION: Some of the above-mentioned leaflets were shipped by Ira Allison or on his instructions, while others were prepared by the consignee.

LABEL, IN PART: (Bottle) "Savoy Mineral Tablets Each Tablet Represents: Manganese sulfate 0.12 Gm., Magnesium sulfate 0.12 Gm., Copper sulfate 1.5 mg., Cobalt sulfate 6 mg., Iron sulfate 30 mg., Zinc sulfate 1 mg." and "Savoy Nutritional Tablets Each Tablet contains: Dicalcium Phosphate (Calcium Phosphate Diabasic) 7½ Grains."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets which accompanied the articles were false and misleading. The statements represented and suggested that the articles were adequate and effective treatments for brucellosis, mastitis, undulant fever, gastric ulcers, symptoms of nervousness, despondency, fear of imminent danger,

incurable eczema, tularemia, many disorders and diseases, swollen joints, stiffness, lumps, tired feeling, lack of pep and energy, a large variety of ailments, eczema, abortions, allergies, arthritis, neuritis, rheumatism, rheumatic fever, asthma, colitis, constipation, marked weakness, gastritis, vertigo, diabetes, marked nervousness, depressions, fears, etc., marked mental trouble apparently melancholia, achlorhydria, pulmonary disturbance, heart trouble, tachycardia, and loss of weight. The articles were not adequate and effective treatments for such conditions. The articles were misbranded in the above respect when introduced into, while in, and while held for sale after shipment in, interstate commerce.

The articles were alleged also to be misbranded when introduced into and while in interstate commerce, under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 12, 1953. The Schrock Bros. Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the leaflets be destroyed and that the *mineral tablets* and the *nutritional tablets* be released under bond for relabeling, under the supervision of the Federal Security Agency.

3916. Misbranding of Gramer's Sulgly-Minol. U. S. v. 138 Bottles, etc. (F. D. C. No. 33578. Sample No. 40741–L.)

LIBEL FILED: September 9, 1952, District of Idaho.

ALLEGED SHIPMENT: On or about August 7, 1952, by C. F. Moore, from Spokane, Wash.

PRODUCT: 138 bottles of a product known as "Gramer's Sulgly-Minol" at Nampa, Idaho, together with the following printed matter, which had been shipped to Nampa, Idaho, previous to the shipment of the product: (1) labels to be attached to the bottles, reading, in part: "4 Fluid Ounces Gramer's Sulgly-Minol A Solution of Sulphur, Glycerine, Sulphurated Lime and Isopropyl Alcohol 6%," (2) yellow circulars headed "Now Try Gramer's Sulgly-Minol," (3) white circulars headed "Gramer's Sulgly-Minol," (4) order sheets headed "Arthritis," and (5) leaflets headed "Dear Sulgly-Minol User."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, consisting of the above-mentioned bottle labels, yellow circulars, order sheets, and leaflets which accompanied the article, was false and misleading. The labeling represented and suggested that the article, diluted with water and used as a foot bath, applied to the soles of the feet or used as a tub bath was an adequate and effective treatment for arthritis and kindred ailments, rheumatic ailments, pains in the hips, legs, heels, ankles, joints of the shoulders, arms, neck, and collarbone, and muscles of the back, legs, and feet, open sores, stiffness and soreness in legs and knees, and boils: that the article was a blood purifier; and that it was a preventive against arthritic and rheumatic conditions. The article, when used as directed, was not an adequate and effective treatment for the conditions stated and implied, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: November 7, 1952. Default decree of condemnation and destruction.

3917. Misbranding of McKay's Maxlin liniment. U. S. v. 92 Cartons, etc. (F. D. C. No. 33905. Sample No. 49748–L.)

LIBEL FILED: October 9, 1952, Southern District of New York.

ALLEGED SHIPMENT: On or about July 1, 1952, by the McKay Maxlin Co., from West Allis, Wis.

PRODUCT: 92 cartons, each containing 1 16-ounce bottle, of *McKay's Maxlin liniment* at New York, N. Y. Each carton contained a circular entitled "McKay's Maxlin Liniment For Best Results, Follow Directions Carefully."

LABEL, IN PART: (Carton) "Contains 16 Fluid Ounces McKay's Maxlin * * * Liniment Active Ingredients – Menthol Crystals U. S. P. XI, Oil Wormwood (American), Tincture Iodine U. S. P., Ether U. S. P. (4 oz. by Volume), Soap Liniment U. S. P."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the above-mentioned circular were false and misleading since the article was not effective in the treatment of the conditions suggested and implied and was not capable of fulfilling the promises of benefit made for it, namely, (circular) "McKay's Maxlin Liniment * * * Directions for Use on Tendons, Ligaments, Ankles, Splints, Knees, Shoulders and Hips: Apply with a toothbrush or a small quantity in hand * * * In severe cases of lameness, injured tendons or ligaments, better results are obtained by using a sheet of oiled silk or waxed paper over the painted leg, covered by two or three sheets of cotton. Used in this way it produces a strong, beneficial sweat, which helps to remove soreness and fever * * * Directions For * * * Steaming of Kidneys * * * A few drops rubbed out well between the palms of hands and applied to * * * kidneys * * * provides an excellent steamer."

DISPOSITION: December 16, 1952. Default decree of condemnation and destruction.

3918. Misbranding of pine needle bath oil. U. S. v. 288 Bottles, etc. (F. D. C. No. 33069. Sample No. 13932–L.)

LIBEL FILED: April 22, 1952, District of Colorado.

ALLEGED SHIPMENT: On or about February 19, 1952, by House of Pine, Balpine, Inc., from Buffalo, N. Y.

PRODUCT: 288 4-ounce bottles, 88 8-ounce bottles, 48 16-ounce bottles, and 5 32-ounce bottles of *pine needle bath oil* at Denver, Colo.

LABEL, IN PART: "Balpine Pine Needle Bath Oil Concentrate."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label of the article were false and misleading. The statements represented and suggested that the article would be effective for skin, nerve, muscle, and circulatory disorders, and that the article would induce sound sleep, relieve tiredness, calm the nerves, and stimulate and invigorate the body. The article was not effective in the treatment of these conditions nor for the purposes mentioned.

DISPOSITION: December 10, 1952. The May Co., Denver, Colo., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

3919. Misbranding of Caragol. U. S. v. 18 Cartons * * *. (F. D. C. No. 31667. Sample No. 7188–L.)

LIBEL FILED: September 6, 1951, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about May 15, June 15, and July 20, 1951, by Caragol Laboratories, Inc., from Cleveland, Ohio.

PRODUCT: 18 cartons, each containing 16 4-ounce bottles and 6 1-ounce bottles, of *Caragol* at Pittsburgh, Pa.

LABEL, IN PART: (Bottle) "Caragol (Linimentum Caragolis) Active Ingredients: Menthol, Camphor, Oil Wintergreen (Synthetic) Extract Capsicum."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in the circular wrapped around the 1-ounce bottles represented and suggested that the article was an adequate and effective treatment for sprains, strains, muscular aches and pains, stiff neck, back strain, lumbago, burns, bruises, frostbite, sunburn, rheumatism, arthritis, and neuritis, whereas the article would not be effective for such purposes.

DISPOSITION: March 30, 1953. Caragol Laboratories, Inc., having filed an answer denying that the product was misbranded and subsequently having stated that it did not wish to contest the action, judgment of condemnation was entered. The court ordered that the product be delivered to a local hospital.

3920. Misbranding of MacLevy hand massagers. U. S. v. 5 Devices, etc. (F. D. C. No. 34144. Sample No. 14581-L.)

LIBEL FILED: November 17, 1952, District of Utah.

ALLEGED SHIPMENT: On or about July 8, 1952, by the MacLevy Equipment Corp., from New York, N. Y.

PRODUCT: 5 *MacLevy hand massagers* and a number of leaflets entitled "Reduce At Home" at Salt Lake City, Utah. The device consisted of 4 rubber balls mounted on a metal shaft with a handle at each end.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflet accompanying the device were false and misleading. The statements represented and suggested that the device would be effective to bring about a reduction in weight, whereas the device would not be effective for that purpose.

DISPOSITION: December 29, 1952. Default decree of condemnation. The court ordered that the devices and leaflets be delivered to the Food and Drug Administration.

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[1] (3912) Permanent injunction issued.
[2] (3911) Contains opinion of the court.

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ERRATUM

Change heading of Drugs and Devices Notice of Judgment No. 3848 to:

3848. Alleged misbranding of Seconal Sodium capsules and pentobarbital sodium capsules. U. S. v. Webb's City, Inc., and Charles L. Fox. Pleas of not guilty. Motion for dismissal of the information granted and defendants discharged as not guilty.

U. S. GOVERNMENT PRINTING OFFICE: 1953

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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3921–3940

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *August 4, 1953.*

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DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3921. Misbranding of methamphetamine hydrochloride tablets, pentobarbital sodium capsules, Tricombisul tablets, thyroid tablets, and Amytal Sodium capsules. U. S. v. Andrew J. Kennedy (Kennedy Drugs), and Paul J. Argust. Pleas of guilty. Fine of $400 against Defendant Kennedy and $200 against Defendant Argust. (F. D. C. No. 33712. Sample Nos. 17021–L, 17048–L, 17325–L, 17563–L, 17567–L.)

INFORMATION FILED: January 13, 1953, Southern District of California, against Andrew J. Kennedy, trading as Kennedy Drugs, Los Angeles, Calif., and Paul J. Argust, a pharmacist employed by Mr. Kennedy.

ALLEGED VIOLATION: On or about May 4, 7, 9, and 11, 1951, and April 22, 1952, while a number of *methamphetamine hydrochloride tablets*, *pentobarbital sodium capsules*, *Tricombisul tablets*, *thyroid tablets*, and *Amytal Sodium capsules* were being held for sale at Kennedy Drugs, after shipment in interstate commerce, various quantities of such drugs were repacked and dispensed without a prescription of a physician, which acts resulted in the repackaged drugs being misbranded.

Defendant Kennedy was charged with causing the repacking and dispensing of the *pentobarbital sodium capsules*, *Tricombisul tablets*, and *Amytal Sodium capsules;* Defendant Argust was charged with causing such acts to be done with respect to the *methamphetamine hydrochloride tablets;* and both of the defendants were charged with causing the repacking and dispensing of the *thyroid tablets.*

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), all of the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* and *Amytal Sodium capsules* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of such repackaged drugs failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *thyroid tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the label of the *methamphetamine hydrochloride tablets* and the *Tricombisul tablets* failed to bear the common or usual name of each active ingredient of such drugs; and, Section 502 (f) (2), the labeling of the repackaged *methamphetamine hydrochloride tablets* and *Tricombisul tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: March 2, 1953. Pleas of guilty having been entered by the defendants, the court fined Defendant Kennedy $400 and Defendant Argust $200.

3922. Misbranding of methamphetamine hydrochloride tablets and pentobarbital sodium capsules. U. S. v. Leslie M. Nelson (Green Lake Pharmacy). Plea of guilty. Fine, $750. (F. D. C. No. 33734. Sample Nos. 29881–L, 29885–L.)

INFORMATION FILED: December 31, 1952, Western District of Washington, against Leslie M. Nelson, trading as the Green Lake Pharmacy, Seattle, Wash.

ALLEGED VIOLATION: On or about October 29 and November 5, 1951, while quantities of *methamphetamine hydrochloride tablets* and *pentobarbital sodium capsules* were being held for sale at the Green Lake Pharmacy, after shipment in interstate commerce, the defendant caused a number of such tablets and capsules to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *methamphetamine hydrochloride tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of such capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the label of the repackaged *pentobarbital sodium capsules* failed to bear the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: March 16, 1953. The defendant having entered a plea of guilty, the court fined him $750.

3923. Misbranding of pentobarbital sodium capsules, Seconal Sodium capsules, and sulfadiazine tablets. U. S. v. Gordon A. Wolf (Wolf Drug Store), and Otto O. Hansen. Pleas of guilty. Fines of $100 against Defendant Wolf and $50 against Defendant Hansen. (F. D. C. No. 33739. Sample Nos. 19315–L, 19327–L, 19328–L, 19333–L, 19357–L, 35014–L, 35015–L, 35028–L.)

INFORMATION FILED: January 21, 1953, Western District of Wisconsin, against Gordon A. Wolf, trading as the Wolf Drug Store, Thorp, Wis., and Otto O. Hansen, a pharmacist.

ALLEGED VIOLATION: On or about January 9, March 20, April 19, May 23, June 20, and July 12, 1951, while a number of *pentobarbital sodium capsules*, *Seconal Sodium capsules*, and *sulfadiazine tablets* were being held for sale at the Wolf Drug Store, after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded.

Gordon A. Wolf was charged as a defendant in each of the 8 counts of the information, and Otto O. Hansen was joined as a defendant in 6 counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use; and, Section 502 (b) (1), a portion of the repackaged *sulfadiazine tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* and *Seconal Sodium capsules* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of the repackaged capsules failed to bear the name, and quantity or proportion of each derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the tablets; and, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: On January 26, 1953, Defendant Wolf having entered a plea of guilty, the court fined him $100. On March 12, 1953, following a plea of guilty by Defendant Hansen, the court fined him $50.

3924. Misbranding of Seconal Sodium capsules and capsules of Seconal Sodium and Amytal Sodium. U. S. v. Snyder's Drug Stores, Inc., and Anthony J. Klenert. Plea of nolo contendere for corporation and plea of guilty for individual. Corporation fined $250 and individual fined $50. (F. D. C. No. 32704. Sample Nos. 19329–L, 35151–L, 35152–L, 35212–L.)

INFORMATION FILED: May 16, 1952, District of Minnesota, against Snyder's Drug Stores, Inc., Minneapolis, Minn. and Anthony J. Klenert, a pharmacist for the corporation.

ALLEGED VIOLATION: On or about May 31 and August 1 and 3, 1951, while a number of *Seconal Sodium capsules* and *capsules of Seconal Sodium and Amytal Sodium* were being held for sale at Snyder's Drug Stores, Inc., various quantities of such drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

The corporation was named as a defendant in all four counts of the information, and the individual was joined as a defendant in three counts and charged with the violation involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drugs contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of such drugs failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use; and Section 502 (e) (2), the label of the *capsules of Seconal Sodium and Amytal Sodium* failed to bear the common or usual name of each active ingredient of the capsules.

DISPOSITION: January 13, 1953. A plea of nolo contendere having been entered by the corporation and a plea of guilty by the individual defendant, the court imposed a fine of $250 against the corporation and a fine of $50 against the individual.

3925. Misbranding of amphetamine sulfate tablets and capsules of Seconal Sodium and Amytal Sodium. U. S. v. Frank A. Harlan (Harlan Drugs). Plea of nolo contendere. Fine of $750, plus costs. (F. D. C. No. 32725. Sample Nos. 18807-L, 18812-L, 18818-L, 18825-L, 18826-L.)

INFORMATION FILED: September 16, 1952, Southern District of Iowa, against Frank A. Harlan, trading as Harlan Drugs, Des Moines, Iowa.

ALLEGED VIOLATION: On or about October 24 and November 2 and 13, 1951, while a number of *amphetamine sulfate tablets* and *capsules of Seconal Sodium and Amytal Sodium* were being held for sale at Harlan Drugs, after shipment in interstate commerce, the defendant caused various quantities of such drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs, with the exception of a portion of the *capsules of Seconal Sodium and Amytal Sodium*, failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), all of the repackaged drugs failed to bear labeling bearing adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *capsules of Seconal Sodium and Amytal Sodium* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *amphetamine sulfate tablets* failed to bear a label containing the common or usual name of each active ingredient of the drug.

DISPOSITION: January 23, 1953. A plea of nolo contendere having been entered by the defendant, the court imposed a fine of $750, plus costs.

3926. Misbranding of methyltestosterone tablets, phenobarbital tablets, dextro-amphetamine sulfate tablets, and Seconal Sodium capsules. U. S. v. Roy T. Walker (Walker Drug Store). Plea of nolo contendere. Fine of $500. (F. D. C. No. 33707. Sample Nos. 15432-L, 15434-L, 15436-L, 15438-L, 15442-L.)

INFORMATION FILED: November 7, 1952, Northern District of Oklahoma, against Roy T. Walker, trading as the Walker Drug Store, Miami, Okla.

ALLEGED VIOLATION: On or about October 8, and 27, 1951, while a number of *methyltestosterone tablets, phenobarbital tablets, dextro-amphetamine sulfate tablets*, and *Seconal Sodium capsules* were being held for sale at the Walker

Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), all of the repackaged drugs, with the exception of a portion of the *phenobarbital tablets*, failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), all of the repackaged drugs failed to bear an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* and *Seconal Sodium capsules* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and such repackaged drugs failed to bear labels containing the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the *methyltestosterone tablets* and *dextro-amphetamine sulfate tablets* were fabricated from two or more ingredients, and they failed to bear labels containing the common or usual name of each active ingredient.

DISPOSITION: January 23, 1953. A plea of nolo contendere having been entered by the defendant, the court imposed a fine of $500.

3927. Misbranding of pentobarbital sodium capsules and methyltestosterone tablets. U. S. v. Martin A. Gluckman (Martin's Drugs). Plea of nolo contendere. Fine of $900, plus costs. (F. D. C. No. 33725. Sample Nos. 15185–L to 15190–L, incl.)

INFORMATION FILED: March 19, 1953, Southern District of Iowa, against Martin A. Gluckman, trading as Martin's Drugs, Council Bluffs, Iowa.

ALLEGED VIOLATION: On or about February 15, 21, and 26, 1952, while a number of *pentobarbital sodium capsules* and *methyltestosterone tablets* were being held for sale at Martin's Drugs, after shipment in interstate commerce, the defendant caused various quantities of such drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *methyltestosterone tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), a portion of the repackaged *methylthestosterone tablets* failed to bear a label containing the common or usual name of the tablets.

DISPOSITION: March 19, 1953. A plea of nolo contendere having been entered by the defendant, the court fined him $900, plus costs.

3928. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Isidor Rosenfeld and George J. Robbins. Pleas of nolo contendere. Fine of $100 against each defendant. (F. D. C. No. 33721. Sample Nos. 24551–L, 24554–L.)

INFORMATION FILED: February 9, 1953, Eastern District of New York, against Isidor Rosenfeld and George J. Robbins, partners in the partnership of the Morton Pharmacy, Long Island City, N. Y.

ALLEGED VIOLATION: On or about May 19 and July 6, 1951, while a number of *dextro-amphetamine sulfate tablets* were being held for sale at the Morton Pharmacy, after shipment in interstate commerce, the defendants caused quantities of the tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the repackaged tablets were fabricated from two or more ingredients, and they failed to bear a label containing the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use.

DISPOSITION: March 18, 1953. Pleas of nolo contendere having been entered, the court fined each defendant $100.

3929. Misbranding of sulfathiazole tablets. U. S. v. Isadore Arthur Shenk (Garden Pharmacy). Plea of guilty. Fine, $150. (F. D. C. No. 32795. Sample Nos. 25359–L, 25360–L, 26638–L, 26639–L.)

INFORMATION FILED: October 15, 1952, Eastern District of Pennsylvania, against Isadore Arthur Shenk, trading as the Garden Pharmacy, Philadelphia, Pa.

ALLEGED VIOLATION: On or about November 7, 13, and 20, 1951, while a number of *sulfathiazole tablets* were being held for sale at the Garden Pharmacy, after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the label of the repackaged drug failed to bear the common or usual name of the drug; and, Sections 502 (f) (1) and (2), the labeling of the repackaged drug failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: April 8, 1953. The defendant having entered a plea of guilty, the court fined him $150.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3930. Adulteration of cantharides and rhubarb root. U. S. v. 4 Crates, etc. (F. D. C. No. 33540. Sample Nos. 38380–L, 38383–L.)

LIBEL FILED: August 22, 1952, Southern District of New York.

ALLEGED SHIPMENT: Imported from various foreign countries between December 6, 1950, and January 25, 1951.

PRODUCT: 4 crates, each containing 549 pounds, of *cantharides*, and 15 drums, each containing 200 pounds, of *rhubarb root* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the articles consisted in whole or in part of filthy substances by reason of the presence of insects. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: January 19, 1953. Default decree of condemnation and destruction.

3931. Adulteration of lobelia herb. U. S. v. 6 Bales * * *. (F. D. C. No. 33539. Sample No. 38385–L.)

LIBEL FILED: August 25, 1952, Southern District of New York.

ALLEGED SHIPMENT: On various dates, from Coeburn, Va., and West Jefferson and Boone, N. C.

PRODUCT: 6 230-pound bales of *lobelia herb* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance by reason of the presence of insect excreta and webbing. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: February 26, 1953. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3932. Adulteration of liver-folic acid-B_{12} injection. U. S. v. 46 Vials * * *. (F. D. C. No. 34077. Sample No. 55237–L.)

LIBEL FILED: September 26, 1952, Northern District of New York.

ALLEGED SHIPMENT: On or about August 26, 1952, by the Addison Laboratories, from Philadelphia, Pa.

PRODUCT: 46 vials of *liver-folic acid–B_{12} injection* at Syracuse, N. Y. Analysis showed that the product was 86 percent deficient in vitamin B_{12}.

LABEL, IN PART: "10 CC. Liver-Folic Acid B–12 Hematopoletic Formula Intramuscular Each CC. Contains Vit. B–12 30 MCGM. (Crystalline)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Each CC. Contains Vit. B–12 30 MCGM."

DISPOSITION: November 18, 1952. Default decree of condemnation and destruction.

3933. Adulteration and misbranding of vitamin B complex. U. S. v. 82 Vials * * *. (F. D. C. No. 34270. Sample No. 36651–L.)

LIBEL FILED: December 1, 1952, Southern District of Ohio.

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*See also No. 3939.

ALLEGED SHIPMENT: On or about June 24, 1952, by the Taylor Pharmacal Co., from Decatur, Ill.

PRODUCT: 82 30 cc.-vials of *vitamin B complex* at Cincinnati, Ohio. Analysis showed that the product contained less than 50 percent of the declared amount of vitamin B_{12} (cyanocobalamin), 78 percent of the declared amount of vitamin B_1 (thiamine hydrochloride), and 68 percent of the declared amount of riboflavin.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, "Each cc. contains * * * cyanocobalamin 1.0 mcgm. * * * thiamine hydrochloride 50 mg. * * * riboflavin 1 mg."

Misbranding, Section 502 (a), the label statement "Each cc. contains * * * cyanocobalamin 1.0 mcgm. * * * thiamine hydrochloride 50 mg. * * * riboflavin 1 mg." was false and misleading as applied to the article, which contained less than those amounts of vitamin B_{12}, vitamin B_1, and riboflavin.

DISPOSITION: December 22, 1952. Default decree of condemnation and destruction.

3934. Adulteration and misbranding of hydrogen peroxide. U. S. v. 35 Cases * * *. (F. D. C. No. 34271. Sample No. 17741-L.)

LIBEL FILED: December 5, 1952, District of Hawaii.

ALLEGED SHIPMENT: On or about November 7, 1952, by the Purepac Corp., from Los Angeles, Calif.

PRODUCT: 35 cases, each containing 12 7⅜-ounce bottles, of *hydrogen peroxide* at Honolulu, T. H.

LABEL, IN PART: "Purepac solution of hydrogen peroxide USP."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, "Solution of Hydrogen Peroxide," the name of which is recognized in the United States Pharmacopeia, and its quality and purity fell below the official standard since it had an abnormal dark tan color, contained excessive heavy metals (7-9 ppm. as lead), and contained extraneous vegetable material in small particles ranging from 0.2 to 2.00 millimeters in length.

Misbranding, Section 502 (a), the label statement "solution of hydrogen peroxide USP" was false and misleading for the article, which failed to conform to the standards prescribed for it in the United States Pharmacopeia.

DISPOSITION: December 29, 1952. American Factors, Ltd., Honolulu, T. H., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3935. Misbranding of Green's Compound. U. S. v. Maurice Greenberg (Green Laboratories). Plea of guilty. Fine of $1,500, plus costs. (F. D. C. No. 33710. Sample Nos. 18973-L, 19403-L, 24889-L.)

INFORMATION FILED: December 19, 1952, Northern District of Illinois, against Maurice Greenberg, trading as Green Laboratories, at Chicago, Ill.

*See also Nos. 3933, 3934.

ALLEGED SHIPMENT: On or about February 5 and 10 and August 11, 1951, from the State of Illinois into the States of Minnesota, Wisconsin, and Pennsylvania.

LABEL, IN PART: "GREEN'S COMPOUND * * * New improved formula: Solvent of Apii Fructus (Celery Fruit) and Hydrated-Glycerin, Sodium Salicylate, Alcohol 6%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in various letters accompanying the article and addressed to customers of the defendant were false and misleading. The statements represented and suggested that the article would be an adequate and effective treatment for arthritis. The article would not be an adequate and effective treatment for arthritis.

DISPOSITION: January 27, 1953. A plea of guilty having been entered, the court fined the defendant $1,500, plus costs.

3936. Misbranding of Gramer's Sulgly-Minol. U. S. v. 32 Bottles, etc. (F. D. C. No. 33916. Sample No. 14047–L.)

LIBEL FILED: October 20, 1952, District of Colorado.

ALLEGED SHIPMENT: On or about May 30, 1952, by the Sulgly-Minol Co., from Spokane, Wash.

PRODUCT: 32 4-ounce bottles of *Gramer's Sulgly-Minol* at Longmont, Colo., together with a number of leaflets entitled "Arthritis Hundreds Claim Its Grip Broken!" and a number of booklets entitled "Now Try Gramer's Sulgly-Minol."

LABEL, IN PART: (Bottle) "Gramer's Sulgly-Minol A Solution of Sulphur, Glycerine, Sulphurated Lime and Isopropyl Alcohol 6%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in the above-mentioned leaflets and booklets accompanying the article were false and misleading. The statements represented and suggested that the article, diluted with water and used as a foot bath, applied to the soles of the feet, or used as a tub bath, was an adequate and effective treatment for arthritis and kindred ailments, rheumatic ailments, pains in the hips, legs, heels, ankles, joints of the shoulders, arms, neck, and collar bone, muscles of the back, and legs and feet. The article when used as directed was not an adequate and effective treatment for the conditions stated and implied, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: November 26, 1952. Default decree of condemnation and destruction.

3937. Misbranding of medicated lollipops and medicated lozenges. U. S. v. 59 Cartons, etc. (F. D. C. No. 34109. Sample Nos. 50816–L, 50817–L.)

LIBEL FILED: November 7, 1952, District of New Jersey.

ALLEGED SHIPMENT: On or about September 17 and November 9, 1951, by Medipop Products, Inc., from Brooklyn, N. Y.

PRODUCT: 59 cartons, each containing 12 boxes, of *medicated lollipops*, and 58 cartons, each containing 12 boxes, of *medicated lozenges*, at Newark, N. J., together with a number of window streamers containing statements relating to the products.

LABEL, IN PART: (BOX) "Medipop Aspirin Medicated Lollypop * * * Not A Confection * * * Ingredients: Aspirin, 2.4 gr.; Sod. Salicylate, ½ gr.; Benzocaine, Sugar, Corn Syrup, Citric Acid, Certified Coloring and Artificial Flavoring" and "Medi-Drop Aspirin Throat Lozenges * * * Not A Confec-

tion * * * Ingredients: Approx: Aspirin 2.4 grains Benzocaine 1/30 grain, Aromatics, certified coloring and artificial flavoring."

NATURE OF CHARGE: *Medicated Lollipops.* Misbranding, Section 502 (a), the labeling of the article contained false and misleading statements. The statements represented and suggested that the article was an adequate and effective treatment for sore throat, colds, hoarseness, painful teething, and the discomfort following tonsillectomy. The article was not an adequate and effective treatment for such conditions.

Medicated Lozenges. Misbranding, Section 502 (a), the labeling of the article contained statements which were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for colds, coughs, hoarseness, and sore throat. The article was not an adequate and effective treatment for such conditions.

DISPOSITION: December 15, 1952. Default decree of condemnation and destruction.

3938. Misbranding of cosmic ray radiator device. U. S. v. 4 Devices * * *. (F. D. C. No. 32975. Sample No. 13725–L.)

LIBEL FILED: March 31, 1952, District of Colorado.

ALLEGED SHIPMENT: By O. A. Kindom, from Minneapolis, Minn.

PRODUCT: *Cosmic ray radiator device.* 4 cases, each containing 1 device, at Denver, Colo. Examination disclosed that the device was a silver disc and that it emitted no cosmic radiation.

LABEL, IN PART: (Engraved on device) "Kindom Multiple Cosmic Rays radiator Increases Vitality Made by O. A. Kindom Minneapolis, Minn."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Kindom Multiple Cosmic Rays radiator" and the statement "Increases Vitality" engraved on the devices were false and misleading since the devices did not emit cosmic radiation and would not increase vitality.

DISPOSITION: January 7, 1953. Dr. W. Eason Williams, Denver, Colo., having filed an exception to the libel and later having withdrawn the exception, judgment of condemnation was entered and the court ordered that the devices be delivered to the Food and Drug Administration.

DRUGS FOR VETERINARY USE

3939. Adulteration and misbranding of Crufolic-12. U. S. v. 35 Vials * * *. (F. D. C. No. 34048. Sample No. 8526–L.)

LIBEL FILED: October 24, 1952, Western District of New York.

ALLEGED SHIPMENT: On or about August 29, 1952, by the Addison Laboratories, from Philadelphia, Pa.

PRODUCT: 35 vials of *Crufolic–12* at Rochester, N. Y. Analysis showed that the product contained less than 8 percent of the declared amount of vitamin B_{12}.

LABEL, IN PART: "10 cc. Multiple-Dose Vial Crufolic–12 Hematopoietic Formula for Treatment of Animals * * * Each cc. contains Vit. B–12 30 mcg. (Crystalline)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Each cc. contains Vit. B–12 30 mcg."

Misbranding, Section 502 (a), the label statement "Each cc. contains Vit. B–12 30 mcg." was false and misleading as applied to the article, which contained less than the stated amount of vitamin B_{12}.

DISPOSITION: December 3, 1952. Default decree of condemnation and destruction.

3940. Misbranding of Campbell's Chemical Mix. U. S. v. 2 Cases * * *. (F. D. C. No. 34114. Sample No. 14539–L.)

LIBEL FILED: November 7, 1952, District of Idaho.

ALLEGED SHIPMENT: On or about October 13, 1952, by the S & L Campbell Co., from Dupont, Colo.

PRODUCT: 2 cases, 1 containing 12 boxes and 1 containing 10 boxes of *Campbell's Chemical Mix* at Buhl, Idaho. Analysis indicated that the product consisted essentially of ammonium chloride, with relatively small proportions of sodium chlorate and potassium chlorate.

LABEL, IN PART: (Box) "Campbell's Chemical Mix For Cattle and Sheep * * * Net Wt. 3 lbs."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading: "Campbell's Chemical Mix For Cattle and Sheep" and (instructions for feeding sheep and cattle on alfalfa or clover) "put one 3-lb. package of Campbell's Chemical Mix to 100 lbs. No. 4 salt and mix thoroughly. Put in troughs where they can have access to it at all times. When feeding dairy cows chop or bran, put ¼ teaspoonful in the chop or bran twice daily out of the 3-lb. package. For drench, mix one teaspoonful in ¾ quart of water and drench. We recommend force feeding when grain is fed—feed about 2 or 3 days before turning on clover or alfalfa." The statements represented and suggested that the article was effective as a remedy for the diseases of cattle and sheep, for any ill effects upon sheep and cattle resulting from eating alfalfa or clover, or upon dairy cows from eating chop or bran, and for preventing ill effects upon cattle from grazing on clover or alfalfa. The article was not effective as a remedy for any diseases of sheep or cattle, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: December 15, 1952. Default decree of forfeiture and destruction.

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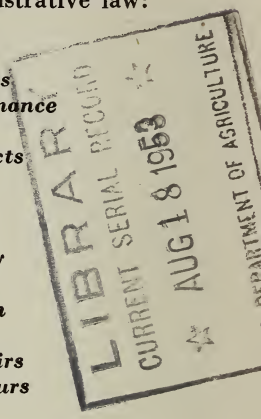
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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3941–3960

DRUGS AND DEVICES

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The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*
WASHINGTON, D. C., *August 11, 1953.*

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263498—53——1

VIOLATIVE SALES OF PRESCRIPTION DRUGS

3941. Misbranding of pentobarbital sodium capsules and methyltestosterone linguets. U. S. v. Harold E. Axtell (Axtell Prescription Pharmacy). Plea of nolo contendere. Fine of $150, plus costs. (F. D. C. No. 33746. Sample Nos. 15212–L, 15214–L to 15217–L, incl., 15221–L.)

INFORMATION FILED: January 28, 1953, District of Nebraska, against Harold E. Axtell, trading as the Axtell Prescription Pharmacy, Beatrice, Nebr.

NATURE OF CHARGE: On or about March 26 and April 7, 12, 18, and 22, 1952, while a number of *pentobarbital sodium capsules* and *methyltestosterone linguets* were being held for sale at the Axtell Prescription Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded as follows: Section 502 (b) (1), the repackaged *pentobarbital sodium capsules* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2) all the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents. Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (e) (2), the repackaged *methyltestosterone linguets* failed to bear a label containing the common or usual name of each active ingredient of the drug; and, Section 502 (f) (1), the labeling of all the repackaged drugs failed to bear adequate directions for use.

Further misbranding, on or about April 28, 1952, while a number of *methyltestosterone linguets* were being held for sale at the Axtell Prescription Pharmacy, after shipment in interstate commerce, the defendant caused a number of the *methyltestosterone linguets* to be dispensed without a prescription from a practitioner licensed by law to administer such drug. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drug being misbranded.

DISPOSITION: February 10, 1953. The defendant having entered a plea of nolo contendere, the court fined him $150, plus costs.

3942. Misbranding of pentobarbital sodium capsules and amphetamine sulfate tablets. U. S. v. Eliot Pharmacy, Inc., and Morris Wernick. Pleas of guilty. Fine of $250 against each defendant. (F. D. C. No. 33853. Sample Nos. 44577–L, 44579–L.)

INFORMATION FILED: January 20, 1953, District of Massachusetts, against the Eliot Pharmacy, Inc., Boston, Mass., and Morris Wernick, treasurer of the corporation.

NATURE OF CHARGE: On or about August 6 and 7, 1952, while quantities of *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were being held for sale at the Eliot Pharmacy, Inc., after shipment in interstate com-

merce, the defendants caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drugs being misbranded.

DISPOSITION: February 24, 1953. Pleas of guilty having been entered, the court imposed a fine of $250 against each defendant.

3943. Misbranding of thyroid tablets and methamphetamine hydrochloride tablets. U. S. v. Herman H. Michelson (Dixie Drugs). Plea of nolo contendere. Fine of $100, plus costs. (F. D. C. No. 33757. Sample Nos. 12383–L, 36193–L, 36627–L.)

INFORMATION FILED: January 28, 1953, Western District of Kentucky, against Herman H. Michelson, trading as Dixie Drugs, Louisville, Ky.

NATURE OF CHARGE: On or about April 3 and 24, 1952, while a number of *thyroid tablets* were being held for sale at Dixie Drugs, after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded as follows: Section 502 (b) (1), a portion of the repackaged *thyroid tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), all the repackaged *thyroid tablets* failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), a portion of the repackaged *thyroid tablets* failed to bear a label containing the common or usual name of the tablets; and, Section 502 (f) (1), the labeling of all the repackaged *thyroid tablets* failed to bear adequate directions for use.

Further misbranding, on or about April 28, 1952, while a number of *methamphetamine hydrochloride tablets* were being held for sale at Dixie Drugs, after shipment in interstate commerce, the defendant caused a number of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drug being misbranded.

DISPOSITION: March 13, 1953. The defendant having entered a plea of nolo contendere, the court fined him $100, plus costs.

3944. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Claude H. Mathis, Sr. (Mathis Drug Store). Plea of nolo contendere. Fine, $50. (F. D. C. No. 33841. Sample Nos. 46520–L, 46521–L.)

INFORMATION FILED: December 5, 1952, Northern District of Mississippi, against Claude H. Mathis, Sr., trading as the Mathis Drug Store, Corinth, Miss.

NATURE OF CHARGE: On or about June 21 and 22, 1952, while a number of *dextro-amphetamine sulfate tablets* were being held for sale at the Mathis Drug Store, after shipment in interstate commerce, the defendant caused a number of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drug being misbranded.

DISPOSITION: April 6, 1953. The defendant having entered a plea of nolo contendere, the court fined the defendant $50.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3945. Misbranding of pentobarbital sodium capsules. U. S. v. Duvall Pharmacy, Inc., and Charles H. Wagner. Pleas of guilty. Fine of $300 against each defendant, plus costs. (F. D. C. No. 33740. Sample Nos. 3995–L, 3996–L, 4009–L.)

INFORMATION FILED: January 23, 1953, District of Maryland, against Duvall Pharmacy, Inc., Baltimore, Md., and Charles H. Wagner, vice president and pharmacist for the corporation.

ALLEGED VIOLATION: On or about November 7 and 13 and December 4, 1951, while a number of *pentobarbital sodium capsules* were being held for sale at Duvall Pharmacy, Inc., after shipment in interstate commerce, the defendants caused various quantities of the capsules to be repacked and dispensed without a prescription, which acts resulted in the repackaged capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use.

DISPOSITION: February 27, 1953. Pleas of guilty having been entered on behalf of the defendants, the court fined each defendant $300, plus costs.

3946. Misbranding of Seconal Sodium capsules. U. S. v. L & S Pharmacy, Inc. (Whelan Drug (Sales Agency)), Stephan Stimac, and James M. Loureiro. Pleas of nolo contendere. Fine of $200 against each defendant. (F. D. C. No. 33755. Sample Nos. 26899–L to 26902–L, incl., 27586–L to 27588–L, incl.)

INFORMATION FILED: February 26, 1953, Northern District of California, against L & S Pharmacy, Inc., doing business as Whelan Drug (Sales Agency), and against Stephan Stimac, president of the corporation, and James M. Loureiro, secretary-treasurer.

ALLEGED VIOLATION: On or about November 21, 23, 26, and 29, and December 4, 5, 6, and 18, 1951, while a number of *Seconal Sodium capsules* were being held for sale at L & S Pharmacy, Inc., after shipment in interstate commerce, the defendants caused various quantities of the *Seconal Sodium capsules* to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing an accurate statement of the quantity of the contents.

*See also Nos. 3941, 3943.

Further misbranding, Section 502 (d), the repackaged capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use.

DISPOSITION: March 30, 1953. Pleas of nolo contendere having been entered by the defendants, the court fined each defendant $200.

3947. Misbranding of Seconal Sodium capsules and amphetamine sulfate tablets. U. S. v. John L. Tarlow (Tarlow Drug). Plea of guilty. Fine, $500. (F. D. C. No. 33800. Sample Nos. 6580–L, 6581–L, 6583–L.)

INFORMATION FILED: February 5, 1953, District of Massachusetts, against John L. Tarlow, trading as Tarlow Drug, at Boston, Mass.

ALLEGED VIOLATION: On or about March 25 and 26, 1952, while a number of *Seconal Sodium capsules* and *amphetamine sulfate tablets* were being held for sale, after shipment in interstate commerce, the defendant caused quantities of the drugs to be dispensed without a physician's prescription, which acts resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the dispensed drugs failed to bear adequate directions for use; and, Sections 502 (b) (1) and (2), the *amphetamine sulfate tablets* and a portion of the *Seconal Sodium capsules* were in package form and failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the *amphetamine sulfate tablets* failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the *amphetamine sulfate tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: February 25, 1953. A plea of guilty having been entered, the court fined the defendant $500.

3948. Misbranding of amphetamine sulfate tablets. U. S. v. Hy-Gold Drug Co., Inc., and Boris Golden. Pleas of nolo contendere. Fine of $200 against corporation and $100 against individual. (F. D. C. No. 33845. Sample Nos. 33542–L, 33546–L, 33554–L, 33567–L.)

INFORMATION FILED: December 16, 1952, Northern District of Illinois, against Hy-Gold Drug Co., Inc., Chicago, Ill., and Boris Golden, manager and secretary-treasurer of the corporation.

ALLEGED VIOLATION: On or about October 9, 15, 19, and 30, 1951, while a number of *amphetamine sulfate tablets* were being held for sale at the Hy-Gold Drug

Co., Inc., after shipment in interstate commerce, the defendants caused various quantities of the tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the label of the repackaged tablets failed to bear the common or usual name of the tablets; and, Sections 502 (f) (1) and (2), the labeling of the repackaged tablets failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: March 17, 1953. Pleas of nolo contendere having been entered on behalf of the defendants, the court fined the corporation $200 and the individual $100.

3949. Misbranding of pentobarbital sodium capsules and amphetamine sulfate tablets. U. S. v. Fred W. Beley (Beley's Pharmacy). Plea of guilty. Fine, $250. (F. D. C. No. 33831. Sample Nos. 29314–L to 29316–L, incl., 30649–L, 30650–L.)

INFORMATION FILED: December 18, 1952, District of Montana, against Fred W. Beley, trading as Beley's Pharmacy, Billings, Mont.

ALLEGED VIOLATION: On or about March 13, 14, 17, and 18, 1952, while a number of *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were being held for sale at Beley's Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *amphetamine sulfate tablets* failed to bear a label containing the common or usual name of the drug; and, Section 502 (b) (1), a portion of the repackaged *pentobarbital sodium capsules* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: December 29, 1952. The defendant having entered a plea of guilty, the court fined him $250.

3950. Misbranding of ergotin-aloe compound pills, ergotin and aloe compound tablets, amphetamine sulfate tablets, and sulfamerazine tablets. U. S. v. Tarlow Pharmacy, Sam Silverman, and Sidney Klein. Pleas of guilty. Fine of $400, plus costs, against defendants jointly. (F. D. C. No. 33847. Sample Nos. 33548–L, 33551–L, 33552–L, 33564–L.)

INFORMATION FILED: December 19, 1952, Northern District of Illinois, against the Tarlow Pharmacy, a partnership, Chicago, Ill., and Sam Silverman and Sidney Klein, partners in the partnership.

ALLEGED VIOLATION: On or about October 17, 18, 19, and 22, 1951, while quantities of *ergotin-aloe compound pills, ergotin and aloe compound tablets, amphetamine sulfate tablets*, and *sulfamerazine tablets* were being held for sale at the Tarlow Pharmacy, after shipment in interstate commerce, the defendants caused various quantities of such drugs to be repackaged and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (e) (1), the repackaged *sulfamerazine tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the repackaged *ergotin-aloe compound pills, ergotin and aloe compound tablets*, and *amphetamine sulfate tablets* failed to bear labels containing the common or usual name of each active ingredient of the drugs; and, Section 502 (f) (2), the repackaged *sulfamerazine tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: February 13, 1953. Pleas of guilty having been entered, the court imposed a fine of $400, plus costs, against the defendants jointly.

3951. Misbranding of dextro-amphetamine sulfate tablets and tablets of sulfadiazine and sulfamerazine. U. S. v. Clay D. Lantz (Lantz Drug Store), and Oscar F. Brown. Pleas of guilty. Fine of $300 against Defendant Lantz and $200 against Defendant Brown. (F. D. C. No. 33855. Sample Nos. 10950–L, 35740–L, 35747–L.)

INFORMATION FILED: February 3, 1953, Southern District of Ohio, against Clay D. Lantz, trading as the Lantz Drug Store, Portsmouth, Ohio, and Oscar F. Brown, a clerk in the drugstore.

ALLEGED VIOLATION: On or about December 26, 1951, and January 8, 1952, while quantities of *dextro-amphetamine sulfate tablets* and *tablets of sulfadiazine and sulfamerazine* were being held for sale at the Lantz Drug Store, after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

Each of the defendants was charged with causing the repackaging and dispensing of the *dextro-amphetamine sulfate tablets*, and, in addition, Clay D. Lantz was charged with causing the repackaging and dispensing of the *tablets of sulfadiazine and sulfamerazine.*

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (e) (2), the repackaged *tablets of sulfadiazine and sulfamerazine* failed to bear a label containing the common or usual name of each active ingredient of the drug; and, Section 502 (f) (2), the labeling of the repackaged *tablets of sulfadiazine and sulfamerazine* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: February 11, 1953. Pleas of guilty having been entered, the court imposed a fine of $300 against Defendant Lantz and a fine of $200 against Defendant Brown.

3952. Misbranding of sulfathiazole tablets. U. S. v. Sam's Cut Rate Drugs, Inc., and Claude E. Wilson and Carl R. Miller. Pleas of nolo contendere. Fine of $100 against corporation, $100 against Defendant Miller, and $50 against Defendant Wilson, plus costs. (F. D. C. No. 33846. Sample Nos. 33549–L, 33555–L, 33556–L, 33563–L.)

INFORMATION FILED: January 22, 1953, Northern District of Illinois, against Sam's Cut Rate Drugs, Inc., Chicago, Ill., and Claude E. Wilson and Carl R. Miller, pharmacists for the corporation.

ALLEGED VIOLATION: On or about October 17, 19, and 21, 1951, while a number of *sulfathiazole tablets* were being held for sale at Sam's Cut Rate Drugs, Inc., after shipment in interstate commerce, various quantities of the tablets were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

The corporation was charged in each of the four counts of the information with causing such acts of repacking and dispensing, and Claude E. Wilson was joined as a defendant in one count and Carl R. Miller was joined as a defendant in the other three counts of the information.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the repackaged tablets failed to bear a label containing the common or usual name of the drug; and, Sections 502 (f) (1) and (2), the repackaged tablets failed to bear labeling containing adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: February 16, 1953. Pleas of nolo contendere having been entered, the court imposed a fine of $100 against the corporation, $100 against Defendant Miller, and $50 against Defendant Wilson, plus costs.

3953. Adulteration and misbranding of various drugs. U. S. v. 1 Bottle, etc. (F. D. C. No. 33580. Sample Nos. 18348–L to 18350–L, incl., 39891–L, 39892–L, 39894–L to 39896–L, incl.)

LIBEL FILED: September 8, 1952, District of Arizona.

ALLEGED SHIPMENT: During July 1952, from Seattle, Wash., to Yuma, Ariz., and thereafter transported to Phoenix, Ariz., via the automobile of William L. Palmer.

PRODUCT: 1 1,000-tablet bottle, 11 500-tablet bottles, and 1 400-tablet bottle of *Tablets No. 105;* 6 1,000-tablet bottles, 11 500-tablet bottles, and 1 250-tablet bottle of *Tablets No. 106;* 49 1,000-tablet bottles of *Tablets No. 146;* 11 1,000-tablet bottles and 1 500-tablet bottle of *Tablets No. 108;* 10 1,000-tablet bottles and 6 500-tablet bottles of *Tablets No. 137;* 20 1,000-capsule bottles of *Dasil Evronal capsules;* 4 1,000-tablet bottles of *Dasil Veratrum Compound tablets;* and 4 1,000-tablet bottles of *Dasil Tu-Tone capsules*, at Phoenix, Ariz.

LABEL, IN PART: "Tablets No. 105 1.25 mg. Estrogenic Substances (Water Soluble) Conjugated Estrogens (Equine) * * * Distributed by Palmer & Co. Seattle, Wash."; Tablets No. 106 0.625 mg. Estrogenic Substances (Water Soluble) Conjugated Estrogens (Equine) * * * Distributed by Palmer & Co. Seattle, Wash."; "Tablets No. 146 Dex-Amo Each Tablet Contains: Dextro Amphetamine Sulfate U. S. P. 5 mg. Amobarbital N. F. ½ gr. (32 mg.) Distributed by Palmer & Co. Seattle, Wash."; "Tablets No. 108 Each Tablet Contains Phenobarbital 15 mg. Aminophyllin 100 mg. Rutin 20 mg. * * * Distributed by Palmer & Co. Seattle, Wash."; "No. 137 Paba-Sal Each Tablet Contains Para-Aminobenzoic Acid (5 gr.) 0.3 gm. (As the Sodium Salt) Sodium Salicylate (5 gr.) 0.3 gm. Enteric Coated Distributed by Palmer & Co. Seattle, Wash."; "Capsules Dasil Evronal 1½ gr. (Sodium Aprobarbital) Palmer & Co. Distributors, Seattle, Wash."; "Dasil Veratrum Compound Tablets Each Tablet Contains: Veratrum Viride ¾ gr. Phenobarbital ¼ gr. Sodium Nitrite 1 gr."; and "Dasil Tu-Tone Vitamin D A super potency Vitamin D Capsule containing 50,000 U. S. P. units of Irradiated Ergosterol. Evron Company, Distributors, Chicago, Ill."

NATURE OF CHARGE: *Tablets No. 105.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess. Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 mg. of estrogens in * * * conjugated form, expressed as sodium estrone sulfate" was false and misleading as applied to the article, which contained less than the declared amount of estrogens in conjugated form. (Analysis disclosed that the article contained 0.76 mg. per tablet of conjugated estrogens, expressed as sodium estrone sulfate.)

Tablets No. 106. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess. Misbranding, Section 502 (a), the label statement "Each tablet contains 0.625 mg. of estrogens in * * * conjugated form, expressed as sodium estrone sulfate" was false and misleading as applied to the article, which contained less than the declared amount of estrogens in conjugated form. (Analysis disclosed that the article contained 0.390 mg. per tablet of conjugated estrogens, expressed as sodium estrone sulfate.)

Tablets No. 146. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess. Misbranding, Section 502 (a), the label statement "Each Tablet Contains: Dextro Amphetamine Sulfate U. S. P. 5 mg. Amobarbital N. F. ½ gr. (32 mg.)" was false and misleading as applied to the article, which contained less than the declared amounts of dextro-amphetamine sulfate and amobarbital. (Anal-

ysis disclosed that the article contained 1.12 mgs. per tablet of amphetamine sulfate and 18.3 mgs. of amobarbital.) Further misbranding, Section 502 (d), the article contained amobarbital, a habit forming derivative of barbituric acid, and the label of the drug failed to bear a statement of the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Tablets No. 108. Misbranding, Section 502 (d), the label of the article failed to bear in juxtaposition with the name and quantity of the habit forming substance, phenobarbital, the statement "Warning—May be habit forming."

Tablets No. 137. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the labeling failed to reveal the purposes for which the article was to be used.

Dasil Evronal capsules. Misbranding, Section 502 (d), the label of the article failed to bear in juxtaposition with the name and quantity of the habit forming substance, sodium aprobarbital, the statement "Warning—May be habit forming."

Dasil Veratrum Compound tablets. Misbranding, Section 502 (a), the label statement "Veratrum Compound Tablets" was misleading as applied to the article, which contained, in addition to veratrum, the drugs phenobarbital and sodium nitrite; and, Section 502 (d), the label of the article failed to bear in juxtaposition with the name and quantity of the habit forming substance, phenobarbital, the statement "Warning—May be habit forming."

Dasil Tu-Tone capsules. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the labeling failed to bear a statement as to the quantity, frequency, or duration of use.

DISPOSITION: December 11, 1952. Default decree of condemnation and destruction.

3954. Misbranding of Femo capsules. U. S. v. 8,000 Capsules, etc. (F. D. C. No. 31326. Sample No. 11178-L.)

LIBEL FILED: July 9, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about February 21, 1951, by the Gelatin Products Div., R. P. Scherer Corp., from Detroit, Mich.

PRODUCT: 8,000 *Femo capsules* and an unknown number of labels intended for use on the article when repackaged, in the possession of the Kumfort Drug Products, trade name of the Lipton Drug Sales Co., Cleveland, Ohio. The article had been shipped in interstate commerce in a drum and had been in part repacked into cartons containing 24 capsules.

LABEL, IN PART: (Drum) "Product #53180 * * * Ingredients in each capsule: Ergot, Powdered USP XII 259.2 mg. Aloin, USP 8.1 mg. Apiol Fluid Green 290 mg. Oil Pennyroyal 28 mg. Cottonseed Oil USP q.s. 10 minims. Warning: This is a dangerous drug which may cause serious or fatal injury unless consumed under adequate and continuous medical supervision. Should not be used by individuals with high blood pressure. Excessive doses or prolonged use may cause gastric disturbances. Should not be used during pregnancy, nor by persons suffering from hemorrhoids, nor in the presence of nausea, vomiting, abdominal pains or other possible signs of appendicitis. Caution: To be dispensed only by or on the prescription of a physician"; (carton) "Femo Perles Original Formula, containing the Emmenagogues, Penny-royal, Oil Tansy, Apiol Fluid, Green, Oil Rue Adult Use

Only Directions: 1 capsule after meals and 1 at bedtime. Contents 24 capsules * * * To be used only by or on the prescription of a physician."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use. The article was misbranded in this respect when introduced into, while in, and while held for sale after shipment in, interstate commerce.

Further misbranding, Section 502 (a), the statement "containing * * * Emmenagogues" borne on the carton was false and misleading since the articles listed when used as directed, were not effective emmenagogues; and Section 502 (e) (2), the carton label failed to bear the common or usual name of each active ingredient contained in the article. The article was misbranded in these respects while held for sale after shipment in interestate commerce.

DISPOSITION: January 27, 1953. The Kumfort Drug Products, trade name of the Lipton Drug Sales Co., having filed an answer to the libel but subsequently having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

3955. Misbranding of Elip tablets. U. S. v. 58 Bags, etc. (F. D. C. No. 33229. Sample No. 37622–L.)

LIBEL FILED: May 8, 1952, Eastern District of New York.

ALLEGED SHIPMENT: On or about February 11, 1952, from Newark, N. J.

PRODUCT: 58 1,200-tablet bags and 141 12-tablet boxes of *Elip tablets*, together with a number of empty boxes labeled, in part, "Elip Tablets," at Baldwin, N. Y., in the possession of the Baldwin Laboratories. Analysis showed that the product consisted of sulfur, rhubarb, and a tartrate.

RESULTS OF INVESTIGATION: The 58-bag lot represented the remaining portion of a bulk shipment of 120,000 tablets which had been shipped to the Baldwin Laboratories, and the 141-box lot represented tablets from the bulk shipment which had been repackaged by the Baldwin Laboratories.

LABEL, IN PART: (Box) "Elip Tablets Active Ingredients: Potassium Bitartrate, Sulfur and Emodin."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Elip Read Backwards Spells Pile" appearing on the box label was false and misleading since the statement represented and suggested that the article was an adequate and effective treatment for piles, whereas such was not the case; Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient since the label failed to declare the presence of rhubarb.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users since the article was essentially a laxative and its labeling failed to warn that frequent or continued use, or use in accordance with the directions "Take 3 tablets with water the first night then 2 tablets every night thereafter," might result in the establishment of dependence upon laxatives to move the bowels.

The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 28, 1953. Default decree of condemnation and destruction.

3956. Misbranding of Dr. De-Pass analgesic compound. U. S. v. 99 Bottles * * *. (F. D. C. No. 33445. Sample No. 21364–L.)

LIBEL FILED: July 2, 1952, Southern District of Mississippi.

ALLEGED SHIPMENT: On or about April 11, 1952, by the Dr. De-Pass Chemical Co., from Chicago, Ill.

PRODUCT: 99 6-ounce bottles of *Dr. De-Pass analgesic compound* at Jackson, Miss.

LABEL, IN PART: "Dr. De-Pass Analgesic Compound * * * Active Ingredients: Potassium Iodide, Solium Salicylate and Sodium Bicarbonate."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in an accompanying newspaper clipping headed "Do You Suffer? From Arthritis Rheumatism," were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for arthritis, rheumatism, swollen wrists and fingers, and difficulty in walking. The article was not an adequate and effective treatment for those conditions.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear an adequate warning against continuing the duration of treatment if a skin rash was produced by the iodide ingredient.

DISPOSITION: November 12, 1952. William Martin, owner of the Dr. De-Pass Chemical Co., requested that the libel action be dismissed on the basis of insufficient evidence, after which the Government's attorney moved for judgment on the pleadings. The court sustained such motion and having found that the product was mislabeled, entered judgment providing for condemnation and destruction of the product.

3957. Misbranding of Niagara devices. U. S. v. 25 Devices, etc. (F. D. C. No. 33887. Sample Nos. 16643–L, 16646–L.)

LIBEL FILED: September 26, 1952, Western District of Missouri.

ALLEGED SHIPMENT: On or about August 9, 1950, and on unknown dates, by Niamco, Inc., from Dallas, Tex.

PRODUCT: 25 *Niagara Hand Unit devices* and 20 *Niagara Portable devices* at Kansas City, Mo., in the possession of the Niagara Equipment Co., together with certain written, printed, and graphic matter consisting of a number of sales manuals entitled "Health Program for Niagara Health Equipment Company," a number of booklets entitled "Sales Talk" and "Niagara The Monarch of Mechano Massage," a number of books entitled "Stories The Feet Can Tell," a number of charts entitled "Zone Therapy Chart," and a number of pamphlets entitled "Niagara Deep Massage." Some of the written, printed, and graphic matter was shipped from Dallas, Tex.; some was printed in Kansas City, Mo.; and the origin of the remainder was not known.

The devices were vibrators. The *Niagara Hand Unit devices* were so designed as to adapt them to be held in the hand while being applied to any part of the body and the *Niagara Portable devices* were designed for resting the feet upon or for sitting or leaning upon.

LABEL, IN PART: "Niagara of Adamsville, Pa. * * * Hand Unit" and "Niagara of Adamsville, Pennsylvania All Purpose Portable Model."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned written, printed, and graphic matter accompanying the de-

vices as labeling were false and misleading. The statements represented and suggested that the devices constituted an adequate and effective means of treatment for disorders of the heart, liver, colon, rectum, kidneys, neck, gallbladder, small intestines, appendix, ileocecal valve, lungs, bronchial tubes, stomach, spine, knees, pituitary gland, eyes, ears, pancreas, adrenals, spleen, bladder, glands, uterus, ovaries, prostate, hip, menstruation, circulation, aorta, larynx, trachea, diaphragm, and mesentery; for constipation, broken arches, misplaced vertebra, common cold, pneumonia, pernicious anemia, simple anemia, astigmatism, glaucoma, burning or itching condition of the eyes, deafness, enlarged tonsils, sore throat, trouble in the throat, troubles in the head, stiff lame neck, sinus trouble, catarrh of the head, sciatica, hay fever, hypothyroidism, exophthalmic goiter, neurasthenia, headache, female trouble, diabetes, asthma, eczema, thrombosis, embolism, indigestion, palpitation, angina pectoris, gallstones, acute gallbladder attacks, jaundice, atrophy, sclerosis, varicose veins, pain in or lameness of the back, impinged nerves, Bright's disease, enlargement or atrophy of the kidneys, floating kidney, dropsy, lumbago, paralysis, hypertension, bursitis, lame, aching, or stiff shoulder, neuritis of the shoulder, lame hip, arthritis, hemorrhoids, enlargement of the prostate, prolapsed rectum, congestion in general, cystitis, tightening of the muscles of the uterus and vagina, menstrual cramps, pains, aches, sluggishness, rheumatism, neuritis, underweight, overweight, nervous tension, fatigue, swollen feet or legs, loss of speech, coronary thrombosis, intermittent claudication, abdominal angina, feet troubles, swollen joints, stiff knee, fibrous swelling or infiltration in the interior of the body, accumulation of fibrous, cartilaginous, or even bony overgrowth in a joint, muscular ailments, and many other ailments or diseases; and that the devices would be effective to throw off poisons in the system, hasten the healing of broken bones, insure a healthy, glowing complexion, effect the same benefits to the user as active exercise, give the body tone and the user vitality and energy, maintain and restore normal functions of the body, and insure good health. The devices did not constitute an adequate and effective means of treatment for such diseases, symptoms, and conditions, and they were not capable of fulfilling the promises of benefit made for them.

Further misbranding, Section 502 (f) (1), the labeling of the devices failed to bear adequate directions for use for the purposes for which they were intended, namely, for the diseases, symptoms, conditions, and purposes for which they were offered and recommended by Mrs. Betty Myers, demonstrator for and on behalf of the consignee, on August 15, 1952, namely, disorders of the kidneys, gallbladder, pituitary thyroid, eyes, ears, colon, liver, and circulation; for congestion, bronchitis, diabetes, arthritis, swollen ankles or legs, varicose veins, hay fever, back troubles, sinusitis, headaches, menstrual cramps, prostate trouble, pains, sluggishness, aches, and growths; and to speed healing of broken bones and to strengthen muscles.

The devices were misbranded in the above respects while held for sale after shipment in interstate commerce.

Disposition: March 27, 1953. The Niagara Equipment Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3958. Misbranding of Ar-Pan-Ex tablets. U. S. v. 29 Bottles, etc. (F. D. C. No. 29067. Sample No. 77207–K.)

LIBEL FILED: April 24, 1950, Southern District of Illinois.

ALLEGED SHIPMENT: On or about March 6, 1950, by the Reed Products Co., from St. Louis, Mo.

PRODUCT: 29 100-tablet bottles of *Ar-Pan-Ex tablets* and 1 window streamer and 3 display cartons entitled "Ar-Pan-Ex" at Collinsville, Ill.

Examination disclosed that a large size of type was used on the label of the product for the names of disease conditions and that smaller type was used for the qualifying expression "For relief of muscular aches and pains commonly associated with."

LABEL, IN PART: (Bottle) "Ar-Pan-Ex Tablets Each Enteric Coated Tablet Contains: Active Ingredients: Sodium Salicylate, Sodium Para Aminobenzoate, Succinic Acid, Calcium Succinate, Vitamin C (Ascorbic Acid), Vitamin B–1 (Thiamin Hydrochloride), Vitamin B–2 (Riboflavin)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article contained prominently displayed statements arranged to represent and suggest that the article was an adequate and effective treatment for arthritis, neuralgia, rheumatism, lumbago, sciatica, neuritis, and bursitis, which statements were misleading since the article was not an adequate and effective treatment for those conditions.

DISPOSITION: February 26, 1953. The libel action having been removed to the Eastern District of Illinois, and the Reed Products Co., claimant, having filed an answer denying the allegations of the libel and later having withdrawn its answer and consented to the entry of a decree, judgement of condemnation was entered and the court ordered that the product be destroyed.

3959. Misbranding of Glan-F. U. S. v. 129 Bottles * * *. (F. D. C. No. 33907. Sample No. 2160–L.)

LIBEL FILED: October 3, 1952, Middle District of North Carolina.

ALLEGED SHIPMENT: On or about March 25, 1952, from Kalamazoo, Mich.

PRODUCT: 129 bottles, each containing 90 tablets, of *Glan-F* at Sanford, N. C., in the possession of the Medical Service Co.

RESULTS OF INVESTIGATION: The article was shipped in bulk and was repackaged into bottles and relabeled by the consignee.

LABEL, IN PART: (Bottle) "Glan-F for the Treatment of the Prostate Gland Active Ingredients: Suprarenal Substance N. F. 118 mgs. ea. tab. Medical Service Company, Sanford, N. C."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in a circular entitled "Glan-F For Men" accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for enlargement of the prostate gland, whereas the article was not an adequate and effective treatment for this condition. The article was misbranded while held for sale after shipment in interstate commerce.

*See also Nos. 3953–3957.

DISPOSITION: February 3, 1953. Default decree of condemnation and destruction.

3960. Misbranding of Butranol. U. S. v. 19 Bottles * * *. (F. D. C. No. 33932. Sample No. 28247–L.)

LIBEL FILED: October 21, 1952, Northern District of California.

ALLEGED SHIPMENT: On or about July 28, 1952, by Berjac Products, from Brooklyn, N. Y.

PRODUCT: 1-ounce bottles of *Butranol* at Sacramento, Calif. There were in the possession of the consignee two letters which had been received from the shipper of the product and which consisted of an undated sales letter beginning with the words "Gentlemen: As a leading drug store distributor in your city" and a letter dated July 22, 1952, confirming the consignee's order for the product and containing the text and insertion dates of advertising to be run in a local newspaper at the expense of the shipper, which advertising contained statements relating to the product.

LABEL, IN PART: (Bottle) "Isotonic Butranol Ephedrine Alkaloid 1.3% Epinephrine HCl 0.01%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned undated letter and in the letter dated July 22, 1952, were false and misleading since the statements represented and suggested that the article was an adequate and effective treatment for sinus afflictions, catarrh, and earache, whereas the article was not an adequate and effective treatment for those conditions.

DISPOSITION: March 16, 1953. Default decree of condemnation and destruction.

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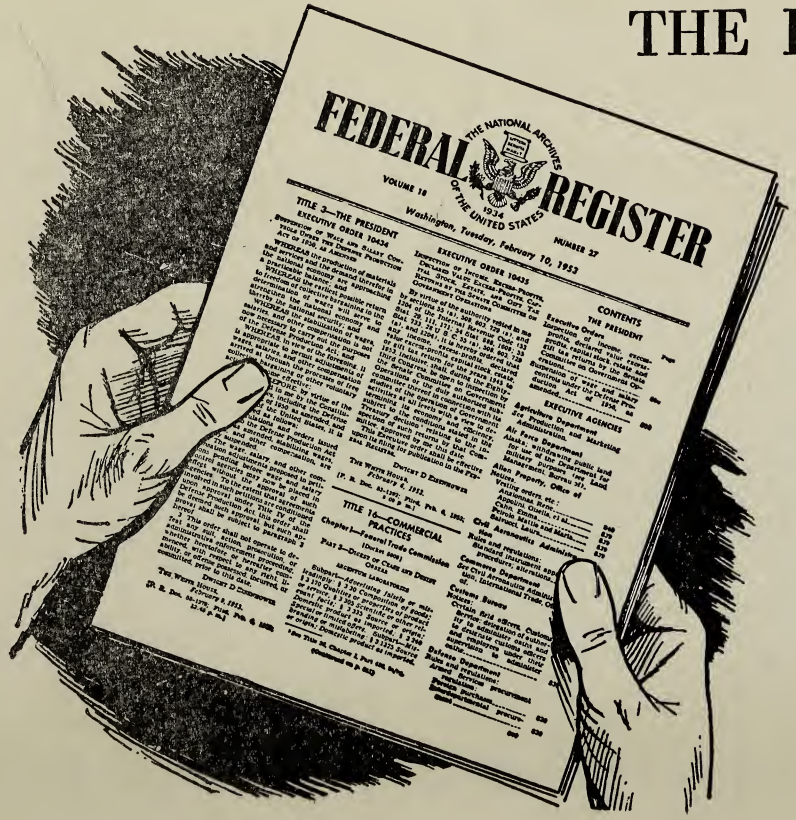
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U. S. GOVERNMENT PRINTING OFFICE: 1953





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332 Nd

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3961–3980

DRUGS AND DEVICES

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The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *August 28, 1953.*

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265401—53——1

VIOLATIVE SALES OF PRESCRIPTION DRUGS

3961. Misbranding of thyroid tablets and methamphetamine hydrochloride tablets. U. S. v. David Rowe. Plea of nolo contendere. Fine of $100, plus costs. (F. D. C. No. 33758. Sample Nos. 12741–L, 36622–L, 36629–L.)

INFORMATION FILED: January 28, 1953, Western District of Kentucky, against David Rowe, a partner in the partnership of the Rowe Drug Store, Louisville, Ky.

NATURE OF CHARGE: On or about April 17 and 24, 1952, while a number of *methamphetamine hydrochloride tablets* and *thyroid tablets* were being held for sale at the Rowe Drug Store, after shipment in interstate commerce, the defendant caused a number of tablets of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded as follows:

Section 502 (b) (1) the repackaged *methamphetamine hydrochloride tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), each of the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (f) (1), the labeling of each of the repackaged drugs failed to bear adequate directions for use; and, Section 502 (f) (2), the labeling of the repackaged *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

On or about April 28, 1952, while a number of *thyroid tablets* were being held for sale at the Rowe Drug Store, after shipment in interstate commerce, David Rowe caused a number of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drug being misbranded.

DISPOSITION: March 13, 1953. The defendant having entered a plea of nolo contendere, the court fined him $100, plus costs.

3962. Misbranding of thyroid tablets, methamphetamine hydrochloride tablets, and tablets containing a mixture of sulfacetimide, sulfadiazine, and sulfamerazine. U. S. v. Frank C. Miller, Sr. (Miller's Drug Store), and Silvio Pesa. Pleas of guilty. Each defendant fined $100, plus costs. (F. D. C. No. 33760. Sample Nos. 12385–L, 36618–L, 36630–L.)

INFORMATION FILED: January 28, 1953, Western District of Kentucky, against Frank C. Miller, Sr., trading as Miller's Drug Store, Louisville, Ky., and Silvio Pesa, a pharmacist.

NATURE OF CHARGE: On or about April 3 and 9, 1952, while a number of *thyroid tablets* and *tablets containing a mixture of sulfacetimide, sulfadiazine, and sulfamerazine* were being held for sale at Miller's Drug Store, after shipment in interstate commerce, Frank C. Miller, Sr., caused a number of *thyroid tablets*, and both of the defendants caused a number of the "sulfa" tablets, to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded as follows:

Section 502 (b) (1), the repackaged "sulfa" tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or

distributor; Section 502 (b) (2), all the repackaged tablets failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (2), the repackaged "sulfa" tablets failed to bear a label containing the common or usual name of each active ingredient of the tablets; and, Sections 502 (f) (1) and (2), the labeling of all the repackaged tablets failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

On or about April 28, 1952, while a number of *methamphetamine hydrochloride tablets* were being held for sale at Miller's Drug Store, after shipment in interstate commerce, Frank C. Miller, Sr., and Silvio Pesa caused a number of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drug being misbranded.

DISPOSITION: March 13, 1953. Plea of guilty having been entered by the defendants, the court fined each defendant $100, plus costs.

3963. Misbranding of diethylstilbestrol tablets and methamphetamine hydrochloride tablets. U. S. v. Harold W. Krupp (Krupp Drug Co.), and Sidney W. Fine. Pleas of nolo contendere. Fine of $100, plus costs, against each defendant. (F. D. C. No. 33759. Sample Nos. 12084-L, 12111-L, 36626-L.)

INFORMATION FILED: January 28, 1953, Western District of Kentucky, against Harold W. Krupp, trading as the Krupp Drug Co., Louisville, Ky., and Sidney W. Fine, a pharmacist.

NATURE OF CHARGE: On or about April 4 and 24, 1952, while a number of *diethylstilbestrol tablets* and *methamphetamine hydrochloride tablets* were being held for sale at the Krupp Drug Co., after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded as follows:

Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the repackaged *diethylstilbestrol tablets* failed to bear the common or usual name of each active ingredient of the drug; and, Sections 502 (f) (1) and (2), the labeling of the repackaged drugs failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users. Harold W. Krupp was charged with causing the acts of repacking and dispensing with respect to each of the drugs, and Sidney W. Fine was joined as a defendant in the count of the information relating to the above-mentioned *methamphetamine hydrochloride tablets*.

On or about April 28, 1952, while a number of *methamphetamine hydrochloride tablets* were being held for sale at the Krupp Drug Co., after shipment in interstate commerce, Harold W. Krupp and Sidney W. Fine caused a number of the tablets to be dispensed without a prescription from a practitioner

licensed by law to administer such drug. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drug being misbranded.

DISPOSITION: March 13, 1953. The defendants having entered pleas of nolo contendere, the court fined each defendant $100, plus costs.

3964. Misbranding of methamphetamine hydrochloride tablets, diethylstilbestrol tablets, methyltestosterone tablets, and dextro-amphetamine sulfate tablets. U. S. v. Barron's Prescription Pharmacy and Arthur J. Barron and Irving A. Barron. Pleas of guilty. Fine of $200 against pharmacy, $100 against Arthur J. Barron, and $50 against Irving A. Barron. (F. D. C. No. 34327. Sample Nos. 11035–L, 35915–L, 36229–L, 36383–L.)

INFORMATION FILED: March 6, 1953, Northern District of Ohio, against Barron's Prescription Pharmacy, a partnership, Cleveland, Ohio, and Arthur J. Barron and Irving A. Barron, partners in the partnership.

NATURE OF CHARGE: On or about May 12 and 16 and June 2 and 9, 1952, while a number of *methamphetamine hydrochloride tablets*, *diethylstilbestrol tablets*, *methyltestosterone tablets*, and *dextro-amphetamine sulfate tablets* were being held for sale at Barron's Prescription Pharmacy, after shipment in interstate commerce, the defendants caused a number of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drugs being misbranded.

DISPOSITION: March 27, 1953. The defendants having entered pleas of guilty, the court fined the pharmacy $200, Arthur J. Barron $100, and Irving A. Barron $50.

3965. Misbranding of dextro-amphetamine sulfate tablets, methyltestosterone linguets, and sulfadiazine tablets. U. S. v. Morris Rosenberg (Beacon Pharmacy). Plea of guilty. Fine, $150. (F. D. C. No. 34347. Sample Nos. 10906–L, 35927–L, 36224–L.)

INFORMATION FILED: March 6, 1953, Northern District of Ohio, against Morris Rosenberg, trading as Beacon Pharmacy, Cleveland, Ohio.

NATURE OF CHARGE: On or about May 12 and 19 and June 6, 1952, while a number of *dextro-amphetamine sulfate tablets*, *methyltestosterone linguets*, and *sulfadiazine tablets* were being held for sale at the Beacon Pharmacy, after shipment in interstate commerce, the defendant caused quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drugs being misbranded.

DISPOSITION: March 27, 1953. The defendant having entered a plea of guilty, the court fined him $150.

3966. Misbranding of amphetamine sulfate tablets and pentobarbital sodium capsules. U. S. v. Floyd L. Rice (Dr. F. L. Rice Clinic). Plea of guilty. Fine, $2,000. (F. D. C. No. 34343. Sample Nos. 61149–L, 61150–L.)

INFORMATION FILED: March 12, 1953, Eastern District of Oklahoma, against Floyd L. Rice, trading as the Dr. F. L. Rice Clinic, Madill, Okla.

NATURE OF CHARGE: On or about November 19, 1952, while a number of *amphetamine sulfate tablets* and *pentobarbital sodium capsules* were being held

for sale at the Dr. F. L. Rice Clinic, after shipment in interstate commerce, Floyd L. Rice caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drugs being misbranded.

DISPOSITION: March 30, 1953. The defendant having entered a plea of guilty, the court fined him $1,000 on each of the two counts of the information.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS *

3967. Action to enjoin and restrain the interstate shipment of a misbranded drug. U. S. v. Tom G. Sanders. Consent decree granting injunction. (Inj. No. 228.)

COMPLAINT FILED: September 19, 1950, Western District of Oklahoma, against Tom G. Sanders, Wanette, Okla.

NATURE OF CHARGE: The defendant had been and was, at the time of the filing of the complaint, delivering and causing to be delivered for introduction into interstate commerce at Wanette, Okla., consignments of an article of drug consisting of ground hoof, horn, or other external animal growth suspended in milk diluted with water and containing small amounts of nitrates.

The complaint alleged that the article was misbranded in the following respects:

Sections 502 (b) (1) and (2), the label of the article failed to bear the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of all the diseases for which it was recommended, namely, cancer, diabetes, heart conditions, ulcers, arthritis, anemia, palsy, gas on the stomach, stomach and kidney trouble, cysts, nervous conditions, and other diseases.

The complaint alleged further that unless restrained the defendant would continue to deliver and cause to be delivered, for introduction into interstate commerce, the misbranded article of drug.

DISPOSITION: October 17, 1950. The defendant having consented to the entry of a decree, the court entered a decree of permanent injunction perpetually enjoining the defendant from directly or indirectly introducing or causing to be introduced, and delivering or causing to be delivered for introduction, into interstate commerce, a drug misbranded as alleged in the complaint.

3968. Contempt proceedings for violation of permanent injunction. U. S. v. Tom G. Sanders. Government's application for citation of defendant for criminal contempt denied. Decision reversed by United States Court of Appeals. Defendant's petition for certiorari denied by Supreme Court. Plea of nolo contendere. Fine, $500. (Inj. No. 228.)

APPLICATION FILED: On May 9, 1951, in the Western District of Oklahoma, the United States attorney filed an application for an order to show cause why the defendant should not be punished for criminal contempt.

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*See also Nos. 3961–3963.

NATURE OF CHARGE: It was alleged in the application that, notwithstanding the provisions of the decree of injunction previously entered against the defendant (see the preceding notice of judgment, No. 3967), the defendant, on January 24 and February 2, 5, and 7, 1951, delivered and caused to be delivered, for introduction into interstate commerce, various quantities of the misbranded drug which was involved in the previous injunction action in that the defendant had sold and delivered, for introduction into interstate commerce, quantities of the drug to various purchasers at Wanette, Okla., with the knowledge that the purchasers intended to and would return to their homes at Garden City, Kans., Denison, Tex., and Kansas City, Mo.

It was further alleged that, after the entry of the decree of permanent injunction, the defendant ostensibly discontinued the practice of using salesmen or so-called "runners" to solicit and fill orders from customers outside the State of Oklahoma, and had adopted the practice of selling and delivering the misbranded drug at Wanette, Okla., directly to out-of-State customers, knowing that the misbranded drug would be transported in interstate commerce by such purchasers for use in other States; and that the defendant was thereby disregarding and circumventing the decree of permanent injunction.

DISPOSITION: On July 27, 1951, the defendant having denied that the activities in which he was then engaged constituted an introduction of the drug into interstate commerce, or a delivery of the drug for introduction into interstate commerce, and the court having considered the arguments and briefs of counsel, the following opinion was handed down by the court:

WALLACE, *District Judge:* "This is a criminal contempt proceeding under Section 302 (b) of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 52 Stat. 1040, 21 U. S. C. A. 301 et seq. Judgment for defendant and contempt order denied.

"Defendant, Tom G. Sanders, a resident of the State of Oklahoma, was perpetually enjoined by this court under authority of Section 302 (a) of the Act on October 17, 1950, from 'directly or indirectly introducing or causing to be introduced, and delivering or causing to be delivered, for introduction into interstate commerce, in violation of 21 U. S. C. A. 331 (a), a drug which is misbranded within the meaning of 21 U. S. C. A. 352 [502] (b) (1), 352 (b) (2), 352 (e) (2), or 352 (f) (1).' The injunction was not contested by defendant, and no testimony was heard. This court determined that defendant was engaged in interstate commerce, inasmuch as he had employed 'runners' or 'drummers' who would go into other states and take orders for the drug manufactured by defendant.

"Upon issuance of the injunction order, defendant returned to his home at Wanette, Oklahoma, and continued to distribute and sell his 'home remedy' in the same manner as before, with the exception that he no longer employed 'runners,' but merely sold the drug to such persons as personally came to his home and purchased the product there. Many of these customers were from out-of-state, and defendant was fully aware of this fact. The Government thereupon requested this court to cite the defendant for criminal contempt based upon an alleged violation of the injunction order. Defendant acknowledges and stipulates that the drug is misbranded as provided in the Act, and as alleged by the Government, but denies that the activities in which he is presently engaged constitute an introduction of the drug into interstate commerce, or a delivery of the drug for introduction into interstate commerce, as prohibited by this court's injunction order.

"It therefore appears that the determinative issue before this court is whether or not defendant, by selling his product to persons whom he knew to be residents of another state, but who personally came to defendant's home to make their purchases, was engaged in interstate commerce. So far as this court can determine, this is a matter of first impression, and one upon which there are no cases directly in point.

"At the time of the adoption of the United States Constitution, the 'Commerce power' was relatively unimportant. However, it has so expanded in significance and application that, today, it is certainly one of the most powerful means of Federal regulation. There exists considerable controversy as to whether this expanded application is desirable for the protection of the nation's welfare, or whether it is totally unwarranted and creates an invasion of the regulatory powers of the sovereign states. This difference of opinion is a political issue which is not before this court for determination. We have only to determine whether, under this unique factual situation, the defendant has engaged in interstate commerce.

"An accurate, all-inclusive definition of interstate commerce has never been formulated by the courts. Nor do we attempt such a definition here, for its facets are far too numerous and diverse. However, it is the opinion of this court that certain essential elements must exist before the sales made by the defendant can be classified as constituting interstate commerce. In the case of Carter v. Carter Coal Co., 298 U. S. 238, 298, Mr. Justice Sutherland, in delivering the opinion of the court, stated:

> As used in the Constitution, the word "commerce" is the equivalent of the phrase "intercourse for the purposes of trade," and includes transportation, purchase, sale, and exchange of commodities between the citizens of the different states.

Thus we see that three fundamental elements must exist before the transaction becomes affixed with the character of 'interstate commerce.' First, there must be the element of a sale or exchange. Second, the transaction must be between citizens of different states, or one which creates commercial traffic between different states. Third, there must be the element of transportation. In the case at bar we find that two of these elements have assuredly been satisfied; namely, there has been a sale between citizens of different states. The existence of the element of transportation is not so readily determined. To begin with, there is some question as to what is the requisite transportation. It is almost axiomatic that the transportation intended must be that between states, and not merely that within a single state. However, actual transportation need not have occurred before the transaction becomes endowed with the attributes of interstate commerce. It is enough that a party 'sells and ships, or contracts to sell and ship, the commodity to customers in another state * * *.' (Carter v. Carter Coal Co., supra, p. 303.) Defendant has not, since the rendition of the injunction order, personally shipped or contracted to ship any of his product to persons in other states. The Government takes the position that the mere culmination of a sale between citizens of different states constitutes interstate commerce, where the purchaser, to the knowledge of the vendor, may return to his native state with the product. This court cannot believe that such a broad application of the Commerce power was ever intended, nor that it is justified under the Constitution. It has previously been determined by the Supreme Court that a product merely in the stage of production is not subject to the Commerce power even though it is fully intended that it shall subsequently be transported to another state. (Carter v. Carter Coal Co., supra.) Nor does this court believe that the mere sale of goods constitutes interstate commerce, unless there is an actual movement out of the state, or such is the purpose and intent of both parties in making the sale. However, the Government cites a number of cases which it contends bear out its assertion that defendant is engaged in interstate commerce. A few of the most important of these cases will be considered.

"The Government cites the case of Dahnke-Walker Co. v. Bondurant, 257 U. S. 282. In that case sale was made in Kentucky, the state of the vendor, to a citizen of the State of Tennessee, the product being delivered to the purchaser in Kentucky. The Supreme Court ruled that the transaction was in interstate commerce. From this, the Government has deduced a rule whereby all such sales between citizens of different states will constitute interstate commerce. However, counsel overlook the fact that the delivery of the commodity in question was made on board the cars of a common carrier, in continuance of a long established practice whereby the commodity was to be immediately forwarded to the purchaser's mill. The contract

required delivery on board the cars of a public carrier for that very purpose. The Supreme Court considered these facts to be of the utmost importance, for Mr. Justice Van Devanter stated in the opinion of the court:

> The state court, stressing the fact that the contract was made in Kentucky and was to be performed there, put aside the further facts that the delivery was to be on board the cars and that the plaintiff, in continuance of its prior practice, was purchasing the grain for shipment to its mill in Tennessee. We think the facts so neglected had a material bearing and should have been considered. *They showed that what otherwise seemed an intrastate transaction was a part of interstate commerce.* [Emphasis added.]

The latter portion of Mr. Justice Van Devanter's statement leaves with this court the understanding that had it not been for the *established* practice of the purchaser and vendor, taken into consideration with the delivery of the grain to a common carrier, the court would have determined this transaction to be wholly *intra*state. There is no such similarity of conditions under the facts of the case now before this court. Mere knowledge that the purchaser is a citizen of another state cannot possibly establish such a practice. Delivery was made at the residence of the defendant, personally, to the purchaser. For this court to determine that defendant must inquire into the citizenship of every customer would be to place an intolerable burden upon all persons who sell to the general public. Instead, this court must look to the immediate end which the parties to the transaction have in view. Was it the purpose of the parties to place the commodity within the stream of commerce and transport it to another state? Here, the immediate end in view is to sell the product; how the purchaser uses it or where he takes it is of no concern to the defendant. The fact that defendant was aware that some of his customers were residents of another state does not alter this rule.

"Another case relied upon by the Government is United States v. Dr. Charles Kaadt, 7 Circ., 171 F. 2d 600. In that case the defendant operated a clinic in Indiana for the treatment of diabetics. When persons who had come to the clinic for treatment, returned to their homes in other states, Dr. Kaadt shipped them a special drug, which was misbranded under the provisions of the Federal Food, Drug, and Cosmetic Act. Dr. Kaadt was charged with such practices in five counts. There is some confusion as to the exact facts concerned in the next two counts, but we shall adopt the most charitable interpretation possible to the Government's case. In these two instances, Dr. Kaadt delivered the drug to the patients *before* they left the clinic and they personally carried it into their home state. All of these counts were upheld as being violative of the Federal Food, Drug, and Cosmetic Act. However, that case is not determinative of the issues before the court, for Dr. Kaadt had already placed the sale within the category of interstate commerce, by reason of the fact that he had earlier mailed letters to the purchasers in their home states, advertising the drug and directing the manner in which it was to be used. The court expressly found that these letters constituted part of the misbranding with which the defendant was charged. In the case before this court, defendant has not engaged in such a practice.

"The case of Currin v. Wallace is relied on by the Government to support the rule that where goods are purchased in one state for the purpose of transporting them to another, then the sale is as much a part of interstate commerce as is the transportation. This premise is undeniably sound and one with which this court cannot take issue. However, the basic issue here, is whether defendant did in fact sell his product for the purpose of transporting it to another state. The citation of this case assumes the very point at issue.

"Counsel for defendant refer the court to the case of Eastern Air Transport v. Tax Commissioner, 285 U. S. 147, opinion by Mr. Chief Justice Hughes. In that case the State of South Carolina imposed a tax on the sale of aircraft fuel purchased by an air-transport company for use in its planes, which were engaged in interstate commerce. The airline company contended that this tax constituted a burden on interstate commerce. In upholding the tax, the Supreme Court stated:

> * * * The mere purchase of supplies or equipment for use in conducting a business which constitutes interstate commerce is not so identified with that commerce as to make the sale immune from a non-discriminatory tax imposed by the state *upon intrastate dealers.* [Emphasis added.]

In another place, the Court states:

> Treating the tax as an excise tax upon the sales does not change the result in the instant case, *as the sales are still purely intrastate transactions.* [Emphasis added.]

In both of these statements, the court clearly implies that, even though the fuel is to be used in interstate commerce, the transaction between the vendor of the fuel and the operator of the airline company is wholly of an *intra*state character. What the purchaser of the fuel chose to do with the commodity after its purchase was of no concern to the vendor.

"This court is somewhat astonished to find that an independent gasoline dealer doing business at Ardmore, Oklahoma, who sells fuel to a motorist having a Texas license tag on his automobile, becomes engaged in interstate commerce simply because the purchaser may drive on into Texas and burn part of the fuel there. Yet this is the substance of the Government's pretension. There is yet a further anomaly to the Government's position. If a citizen of Oklahoma purchases a piece of wearing apparel in a Kansas City store, does the vendor thereby become engaged in interstate commerce and subject to Federal regulation, even though he is fully cognizant of the purchaser's native state? Obviously, not. Such an extension of the Commerce power would be wholly unwarranted and an invasion of the regulatory rights of the sovereign states.

"Perhaps the activities of the defendant constitute a recognizable evil which should be apprehended. However, great care must be taken so that, by crushing one evil, the courts do not create in its stead an even greater one. Congress possesses no general power to regulate for the promotion of the general welfare. It is limited in its powers to those which are granted it by the Constitution, and these powers must be either expressly given, or arise by necessary implication. (Martin v. Hunter's Lessee, 1 Wheat. 304.)

"It is the opinion of this court that so long as the defendant does not solicit orders for his product in other states, and does not ship or aid in the shipment of his product to another state, but merely sells his product to persons who personally come to his residence, purchase and carry away this remedy, he is not engaged in interstate commerce, even though some of his customers be residents of another state, and this to the knowledge of the defendant. Therefore, we cannot find the defendant to be in contempt of court for violation of the injunction order.

"Counsel are directed to submit a journal entry in conformity with this opinion within ten days from this date."

In accordance with the above opinion, the court, on or about August 17, 1951, handed down its findings of fact and conclusions of law and entered a decree denying the Government's application for a citation for contempt of the injunction. An appeal was taken by the Government to the United States Court of Appeals for the Tenth Circuit, and on May 7, 1952, the following opinion was handed down by that court:

HUXMAN, *Circuit Judge:* "On October 17, 1951, an injunction was entered against appellee, Tom G. Sanders, in the United States District Court for the Western District of Oklahoma, enjoining him from directly or indirectly introducing or causing to be introduced, and delivering or causing to be delivered, for introduction into interstate commerce, in violation of 21 U. S. C. 311 (a), a drug which was misbranded within the meaning of 21 U. S. C. 352 [502] (b) (1), 352 (b) (2), 352 (e) (2), and 352 (f) (1). Thereafter this action was filed in the nature of an application for an order to show cause why he should not be prosecuted for criminal contempt for a violation of the injunction.

"Appellee, defendant below, filed a response to the order to show cause and moved that appellant's application be quashed and that no citation to show

cause be issued. A hearing was had on appellee's motion. Judgment was entered denying appellant's application for a citation to show cause. While the trial court made findings of fact and conclusions of law, they are based entirely upon the allegations of the application for the show cause order and the statements of the parties at the time of the hearing thereof and not upon evidence introduced bearing upon the issue of appellee's guilt. That issue could not be before the court for determination until a show cause order had issued. Neither did the decree of the court attempt to pass upon the guilt or innocence of appellee. It merely denied the application for a show cause order on the ground that the allegations of the application were insufficient to state an offense.

"Appellee's challenge to the jurisdiction of this court on the ground that the judgment of the trial court constituted an adjudication of guilt and is, therefore, not appealable is not well taken. It is clear that the trial court did not try the issue of guilt or innocence of the appellee. It merely passed upon the sufficiency of the allegations of the application to state an offense, if found true.

"An application to show cause why defendant should not be prosecuted for criminal contempt is equivalent to an information charging criminal contempt, under Rule 42 (b) of the Federal Rules of Criminal Procedure, and a criminal contempt proceeding is a criminal case within the meaning of 18 U. S. C. 3731. An order dismissing a criminal contempt proceeding is appealable under the Criminal Appeals Act.[1]

"It is admitted that the drug in question was misbranded. Appellee's position adopted by the court is that his activities do not constitute interstate commerce as prohibited by the injunction. Prior to the injunction, appellee engaged 'runners' or 'drummers' who went into states other than Oklahoma and solicited orders for the drug. After the injunction, this method of doing business was discontinued. Appellee sold only to those who came to his place of business at Wanette, Oklahoma, and delivered the drugs to them there. Many of these customers came from states other than Oklahoma.

"The application for the order to show cause among others alleged that since the issuance of the injunction appellee had at various times and with full knowledge and notice delivered or caused to be delivered for introduction into interstate commerce various quantities of the misbranded drug; that on January 24, 1951, he sold and delivered to Loyd Mangan of Garden City, Kansas, for introduction into interstate commerce two one-quart jars of said misbranded drug, with the knowledge that Mangan intended to and would return to Garden City, Kansas, with said article or drug. The complaint alleged five other specific sales made to out-of-state customers and alleged that all of said sales were made with the knowledge that the purchaser was from out of the state and intended to and would return to his place of residence out of the state with said drugs. It alleged that while appellee ostensibly discontinued the practice of using salesmen or so called 'runners' to solicit and fill orders from customers outside of the State of Oklahoma he had adopted the practice of selling and delivering his products at Wanette, Oklahoma, directly to out-of-state customers, soliciting them to return at later dates for more of the product, knowing that at all times said misbranded drug would be transported in interstate commerce by said purchasers for use in other states; that by such conduct he was disregarding and circumventing the decree and was in truth and in fact continuing to engage in the interstate business in the misbranded drug and was indirectly introducing or causing it to be introduced into interstate commerce, in violation of the injunction. For the purpose of considering the correctness of the trial court's ruling on the motion for dismissal of the application, these allegations stand admitted and must be accepted as the facts.

"As stated by the Supreme Court in United States v. Walsh, 331 U. S. 432, 34, 'The Federal Food, Drug, and Cosmetic Act rests upon the constitutional power resident in Congress to regulate interstate commerce. To the end that the public health and safety might be advanced, it seeks to keep interstate channels free from deleterious, adulterated, and misbranded articles of the specified types. * * * It is in that interstate setting that the various sections of the Act must be viewed.' The Act must be given a reasonable construction

[1] United States v. Goldman, 277 U. S. 229; United States v. Hoffman, 161 F. 2d 881.

to effectuate its salutary purposes. It prohibits not only the introduction into interstate commerce of adulterated articles but also the delivery thereof for introduction into commerce. One is as much a violation of the Act as the other. There is a long line of cases beginning with Dahnke-Walker Co. v. Bondurant, 257, U. S. 282, holding that where one purchases goods in one state for transportation to another the interstate commerce transaction includes the purchase as well as the transportation.[2] The court sought to distinguish the Dahnke-Walker case on the ground that the wheat purchased by a resident of Tennessee in Kentucky for transportation to Tennessee was delivered by the vendor to the vendee on board the cars of a common carrier, to be immediately forwarded to the purchaser's mills in Tennessee. The decisions, however, make it clear that whether delivery for transportation is made to a common carrier, a private carrier, or even to the purchaser for transportation by himself is immaterial.[3]

"To be guilty of violating the Act, it was not necessary that appellee be engaged in interstate commerce with respect to a misbranded drug. It was sufficient if he was engaged in delivering such a drug for introduction into interstate commerce. If appellee knowingly and regularly sold misbranded drugs and delivered them, knowing that they were purchased for transportation in interstate commerce, and solicited customers to return for future purchases and deliveries, he was guilty of a violation of the Act. The allegations of the complaint for a show cause order alleged that he did all of this and for the purpose of the motion they stand admitted as true. We accordingly conclude that stated an offense and that the trial court erred in dismissing the application for a show cause order.

"The judgment is reversed and the cause is remanded with directions to proceed in conformity with the views expressed herein."

Subsequently a petition for a writ of certiorari was filed by the defendant, and on October 13, 1952, this petition was denied. Thereafter, on February 4, 1953, the case came on for hearing before the United States District Court for the Western District of Oklahoma, and upon a plea of nolo contendere by the defendant, the court fined him $500.

3969. Misbranding of amphetamine sulfate tablets and pentobarbital sodium capsules. U. S. v. Irving Smith (Corner Drug Store), and Nathan Fleishman. Pleas of guilty. Each defendant placed on probation for 2 years; Defendant Smith fined $500. (F. D. C. No. 33797. Sample Nos. 6081–L to 6083–L, incl., 6131–L, 6132–L, 6157–L, 6251–L, 6275–L.)

INFORMATION FILED: February 5, 1953, District of Massachusetts, against Irving Smith, trading as the Corner Drug Store, Boston, Mass., and Nathan Fleishman, a pharmacist.

ALLEGED VIOLATION: On or about October 25, 26, and 29, and November 5, 12, and 15, 1951, while a number of *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were being held for sale at the Corner Drug Store, after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

Irving Smith was charged with causing the acts of repacking and dispensing alleged in each of the eight counts of the information, and Nathan Fleishman was joined as a defendant in two of the counts.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity

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[2] Addyston Pipe & Steel Co. v. United States, 175 U. S. 211; United States v. Rock Royal Co-op, 307 U. S. 533; United States v. Simpson, 252 U. S. 465; Carter v. Carter Coal Co., 298 U. S. 238; United States v. 7 Barrels, etc., 141 F. 2d 767.

[3] United States v. Simpson, 252 U. S. 465; Tobin v. Grant, 79 F. Supp. 975.

of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *amphetamine sulfate tablets* failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the repackaged *amphetamine sulfate tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: April 6, 1953. Pleas of guilty having been entered by the defendants, the court placed each defendant on probation for two years and fined Defendant Smith $500.

3970. Misbranding of dextro-amphetamine sulfate tablets and Seconal Sodium capsules. U. S. v. Lonnie Jackson (Jackson's Drug Store). Plea of guilty. Fine, $500. (F. D. C. No. 34358. Sample Nos. 31034–L, 34327–L, 34388–L.)

INFORMATION FILED: February 24, 1953, Western District of Missouri, against Lonnie Jackson, trading as Jackson's Drug Store, Springfield, Mo.

ALLEGED VIOLATION: On or about March 21 and 26, 1952, while a number of *dextro-amphetamine sulfate tablets* and *Seconal Sodium capsules* were being held for sale at Jackson's Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *Seconal Sodium capsules* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *dextro-amphetamine sulfate* tablets failed to bear a label containing the common or usual name of each active ingredient of the drug.

DISPOSITION: April 7, 1953. The defendant having entered a plea of guilty, the court fined him $500.

3971. Misbranding of Metandren tablets, Amytal Sodium capsules, and Pentresamide tablets. U. S. v. King Cut Rate Drugs, Inc., and Joe Goldberg. Plea of nolo contendere by corporation and plea of guilty by individual. Fine of $250 against corporation and $500 against individual. (F. D. C. No. 34350. Sample Nos. 34361–L, 34368–L, 34800–L.)

INFORMATION FILED: March 19, 1953, Southern District of Illinois, against King Cut Rate Drugs, Inc., Quincy, Ill., and Joe Goldberg, president of the corporation.

ALLEGED VIOLATION: On or about March 13 and 19, 1952, while a number of *Metandren tablets*, *Amytal Sodium capsules*, and *Pentresamide tablets* were being held for sale at King Cut Rate Drugs, Inc., after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Amytal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *Pentresamide tablets* failed to bear a label containing the common or usual name of each active ingredient of the tablets.

DISPOSITION: April 16, 1953. A plea of nolo contendere having been entered by the corporation and a plea of guilty by the individual, the court fined the corporation $250 and the individual $500.

3972. Misbranding of Femo tablets and Femo pills. U. S. v. 24,000 Tablets, etc. (F. D. C. No. 31325. Sample Nos. 11176–L, 11177–L.)

LIBEL FILED: July 9, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about January 19 and 30 and May 25, 1951, by the Chicago Pharmacal Co., from Chicago, Ill.

PRODUCT: 24,000 *Femo tablets* and 12,000 *Femo pills*, together with an unknown number of labels intended for use upon the articles when repackaged, in the possession of the Lipton Drug Sales Co., Cleveland, Ohio. The tablets had been shipped in interstate commerce in drums, and the pills had been shipped in bottles. Portions of both products had been repacked by the consignee, the Lipton Drug Sales Co., into cartons, each containing 24 tablets or pills.

LABEL, IN PART: (Drums in which tablets were shipped) "Ergot, Aloin and Cotton Root Bark Compound No. 2 * * * Ergot Extract 0.5 gr Aloin 0.125 gr Cotton Root Bark Extract 0.5 gr Apiol 0.25 min Oil Pennyroyal 0.01 min Caution: To be dispensed only by or on the prescription of a physician. Warning: For temporary use only and as needed; and not for habitual use. Warning: Ergot is contraindicated in pregnancy, high blood pressure, vascular disease, coronary sclerosis and puerperal infection."

(Bottles in which pills were shipped) "Ergot Cotton Root Bark and Apiol Compound * * * Ergot ½ gr Warning: Ergot is contraindicated in pregnancy, high blood pressure, vascular disease, coronary sclerosis and puerperal infection. Ext. Cotton Root Bark ½ gr Apiol ¼ min Pulsatilla ¼ gr Oil Pennyroyal 1/10 min Caution: To be dispensed only by or on the prescription of a physician."

(Cartons containing tablets) "Femo Pills Special formula containing the Emmenagogues Ergot, Aloin, Extract of Cotton Root Bark, Apiol, and Oil Pennyroyal (Adult Use Only) Directions: 1 capsule after meals and at bedtime. Contents 24 Capsules * * * To be used only by or on the prescription of a Physician."

(Cartons containing pills) "Super Femo Pills Original formula containing the Emmenagogues Extract Ergot, Extract Cotton Root Bark, Apiol, Pulsatilla, and Oil of Pennyroyal (Adult Use Only) Directions: 1 capsule after meals and 1 at bedtime. Contents 24 Pills * * * To be used only by or on the prescription of a physician."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the tablets and pills failed to bear adequate directions for use. The articles were misbranded in this respect when introduced into, while in, and while held for sale after shipment in, interstate commerce.

Further misbranding, Section 502 (a), the statement "containing * * * Emmenagogues" borne on the cartons containing the repackaged tablets and pills was false and misleading since the articles, when used as directed, were not effective as emmenagogues. The articles, were misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: January 27, 1953. The Lipton Drug Sales Co. having filed an answer to the libel, but subsequently having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be destroyed.

3973. Misbranding of Cheno herb tea laxative, Cheno preparation of Phytolacca berries, and Cheno combination tablets. U. S. v. 26 Cartons, etc. (F. D. C. No. 18986. Sample Nos. 36073–H to 36075–H, incl.)

LIBEL FILED: January 21, 1946, Western District of Oklahoma; amended on or about March 14, 1947.

ALLEGED SHIPMENT: In September, November, and December, 1945, and on or about January 14, 1946, by the Alberty Food Products Co., from Hollywood, Calif.

PRODUCT: 26 cartons of *Cheno herb tea laxative*, 24 bottles of *Cheno preparation of Phytolacca berries*, and 8½ dozen cartons of *Cheno combination tablets* at Oklahoma City, Okla.

LABEL, IN PART: "Cheno Herb Tea Laxative Contains: Active laxative ingredient Senna * * * Dosage: Depends upon the individual. Use from one to three teaspoonfuls. Make tea by boiling herbs in a cupful of water. Remove from fire, cover and let steep fifteen minutes or all day; strain before drinking * * * Use as occasionally required for relief of temporary constipation," "Cheno Preparation of Phytolacca Berries * * * App. 50% of Liquid Berry Juice * * * Directions: 6 drops, 3 times daily 15 minutes before each meal in one-half glass of water," and "10 Grain Cheno Combination Tablets * * * Directions: Four tablets before meals, as a supplementary Food source of Calcium, Phosphorus, Iron and Iodine. Cheno

Contains: Dehydrated Parsley, Swiss Chard, Dulse, Irish Moss, Spinach, Psyllium, Di-calcium, Phosphate and Iron Phosphate."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in causing reduction of body weight, which was the condition for which the articles were offered in the advertising disseminated and sponsored by and on behalf of the manufacturer.

DISPOSITION: On March 16, 1946, the libel action was transferred to the Northern District of California. On July 7, 1947, upon a motion of the claimant, the Alberty Food Products Co., the United States District Court for the Northern District of California entered an order directing the removal of the action to the Southern District of California, the home district of the claimant. Thereafter, upon the basis of a stipulation between the parties, an order was entered vacating the July 7 order of removal. Further proceedings in the case were subsequently postponed pending the disposition of certain other cases under the Federal Food, Drug, and Cosmetic Act against certain products of the claimant.

On October 5, 1951, upon stipulation by the parties that the case presented no questions for adjudication for the reasons that the products had deteriorated by reason of the lapse of time and because the same issues involved in the case were also involved in the injunction suit which had been filed by the Government against the claimant and which was then pending in the court of appeals (see notice of judgment on drugs and devices, No. 3663), and with the consent of the parties, the court ordered that the products be destroyed.

3974. **Misbranding of Elip tablets. U. S. v. 216 Boxes, etc.** (F. D. C. No. 33230. Sample No. 37623–L.)

LIBEL FILED: May 8, 1952, Eastern District of New York.

ALLEGED SHIPMENT: On or about February 11, 1952, from Newark, N. J.

PRODUCT: 216 boxes, each containing 12 tablets, of *Elip tablets*, together with a number of empty boxes labeled, in part, "Elip Tablets" and a number of leaflets headed "Elip The Only Internal Pile Remedy," at Freeport, N. Y., in the possession of the Elip Distributing Corp.

Analysis showed that the product consisted of sulfur, rhubarb, and a tartrate.

RESULTS OF INVESTIGATION: The product was part of a bulk shipment of 120,000 tablets which had been made from Newark, N. J., to Baldwin, N. Y., from where a portion of this shipment was transported to Freeport, N. Y., and was packaged into boxes by the Elip Distributing Corp.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Elip Read Backward Spells Pile" appearing on the box label was false and misleading since the statement represented and suggested that the article was an adequate and effective treatment for piles, whereas such was not the case; Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient since its label failed to declare the presence of rhubarb; and, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users since the article was essentially a laxative and its labeling failed to warn that frequent or continued use, or use in accordance with the directions "Take 3 tablets with water

the first night then 2 tablets every night thereafter," may result in establishment of dependence upon laxatives to move the bowels.

Further misbranding, Section 502 (a), the following statements in the above-mentioned leaflets accompanying the article were false and misleading: "The only internal pile remedy * * * what are piles? Hemorrhoids or piles are actually coils of dilated veins occuring inside or outside the rectal mucous membrane. The causes of piles are many and varied but the most common one is constipation. What does Elip do for piles? The astringent action of Elip gently shrinks the mucous membrane of the rectum which promptly relieves congestion and promotes healing of the affected parts. Elip contains no harmful ingredients, and as a result is highly recommended by physicians." The statements represented and suggested that the article was an adequate and effective treatment for piles and that it was harmless. The article was not an adequate and effective treatment for piles and was capable of causing dependence upon laxatives to move the bowels and, in case of appendicitis, of causing rupture of the appendix.

The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: January 28, 1953. Default decree of condemnation and destruction.

3975. Misbranding of Color-Therm devices. U. S. v. 1 Device (and 2 other seizure actions). (F. D. C. Nos. 34399, 34400, 34439. Sample Nos. 16460–L to 16462–L, incl.)

LIBELS FILED: On or about December 12 and 19, 1952, Northern District of Oklahoma.

ALLEGED SHIPMENT: On or about August 2 and 13 and September 1, 1951, by Fred Gerkey, from Mission, Kans.

PRODUCT: 3 *Color-Therm devices* at Nowata, Vinita, and Delaware, Okla. The device consisted of a unit with six U-shaped tubes and a hand applicator with one straight and two U-shaped tubes for producing colored lights, similar to the so-called neon lights, with electrical connections to operate them.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the devices failed to bear adequate directions for use.

DISPOSITION: December 31, 1952. No claimant having appeared, judgments of condemnation were entered. The court ordered that the devices be dismantled and that any parts of use in the commercial field be sold.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3976. Misbranding of posterior pituitary injection. U. S. v. 15 Vials * * *. (F. D. C. No. 34224. Sample No. 14626–L.)

LIBEL FILED: November 28, 1952, Northern District of Texas.

ALLEGED SHIPMENT: On or about August 3, 1951, from Los Angeles, Calif.

PRODUCT: 15 30-cc. vials of *posterior pituitary injection* at Lubbock, Tex.

*See also Nos. 3972, 3974.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "10 U. S. P. Units per cc" was false and misleading as applied to the article, the potency of which was materially less than 10 U. S. P. units of posterior pituitary per cc. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 26, 1953. Default decree of condemnation and destruction.

3977. Misbranding of Century Oil. U. S. v. 141 Bottles * * *. (F. D. C. No. 34281. Sample No. 40866-L.)

LIBEL FILED: December 4, 1952, District of Oregon.

ALLEGED SHIPMENT: On or about November 24, 1952, by the Central Specialty Co., Inc., from Kansas City, Mo.

PRODUCT: 141 1-ounce bottles of *Century Oil* at Portland, Oreg.

LABEL, IN PART: "Chief Kahdot's Century Oil for external use only * * * Ingredients Oil Pine, Oil Camphor, Oil Mustard, Oil Wintergreen Gum, Camphor, Menthol, Oil Wormwood and Light Mineral Oil."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label of the article bore statements which represented and suggested that the article was an adequate and effective treatment for catarrh, headaches, neuralgia, rheumatism, lame back, stiff neck, sprains, chilblains, cramps of the muscles, swellings, and all soreness and lameness, which statements were false and misleading since the article was not an adequate and effective treatment for these conditions.

DISPOSITION: March 3, 1953. Default decree of condemnation and destruction.

3978. Misbranding of ozone generator. U. S. v. 1 Device, etc. (F. D. C. No. 34131. Sample No. 14624-L.)

LIBEL FILED: November 28, 1952, Northern District of Texas.

ALLEGED SHIPMENT: On or about August 18, 1952, by Mrs. M. M. Stubblefield, from Brea, Calif.

PRODUCT: 1 *ozone generator* at Plainview, Tex., together with 2 accompanying pamphlets entitled "Ozone Therapy by O. M. Justice, M. D." and "Ozone God's Gift to Humanity No. 3 Lecture by J. H. Effenberg, Ps. D., Ph. D." The device consisted essentially of glass tubes that glowed and caused the formation of ozone in the surrounding air when the electrical attachments were connected with a suitable electric current.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying pamphlets were false and misleading. The statements represented and suggested that the device would assist health, prevent disease, act as a specific in many diseases, and was effective in the treatment of adenitis, swelling of the breasts, angina pectoris, alopecia, falling of the hair, arthritis, asthma, arteriosclerosis, backache, biliousness, bronchitis, bursitis, colitis, colds, sore chest, constipation, dandruff, deafness, erysipelas, earache, eczema, high blood pressure, indigestion, jaundice, leucorrhea, mumps, nervousness, pleurisy, prostate trouble, pneumonia, pelvic disturbances, psoriasis, quinsy, sore throat, rheumatism, rectal disturbances, sleeplessness, sinus trouble, tuberculosis, varicose veins, wrinkles, infections and diseases of body cavities and passages, chlorosis, anemia, nervous prostration, chronic nasopharyngeal catarrh, whooping cough (pertussis), diphtheria, scarlet fever,

pernicious anemia, cardiovascular and renal diseases, insomnia, hay fever, dyspepsia, headaches, inactive liver and kidneys, syphilis, and rheumatism of gonococcal origin. The device was not capable of fulfilling the promises of benefit made for it, and it was not effective in the treatment of the diseases and conditions stated and implied.

DISPOSITION: January 30, 1953. Default decree of forfeiture. The court ordered that the device and the pamphlets be delivered to the Federal Security Agency.

DRUGS FOR VETERINARY USE

3979. Misbranding of Nutrels. U. S. v. 17 Bags * * *. (F. D. C. No. 31396. Sample No. 7856–L.)

LIBEL FILED: July 25, 1951, Western District of Pennsylvania.

ALLEGED SHIPMENT: The product was shipped on or about Jaunary 6, 1951, by the Martin-Anderson Co., from Oak Ridge, Tenn., and a number of leaflets relating to the product were shipped at various times by Inorganic Bioelements, Inc., from Cleveland, Ohio.

PRODUCT: 17 100-pound bags of *Nutrels* at St. Marys, Pa., together with a number of leaflets entitled "The New Frontier of Agriculture," "The Role of Manganese," "Just A Trace May Help Your Stock," "Good-Bye Bang's Disease," and "Bang's Disease and Undulant Fever."

Analysis of the product disclosed the presence of inorganic salts, principally a manganese compound.

LABEL, IN PART: (Bag) "Ingredients: Manganese, copper, cobalt, zinc, magnesium sulfate, anise & molasses."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets which accompanied the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for brucellosis (Bang's disease in cattle), mastitis (garget in pigs), many breeding troubles, irritability, lack of nerve control, poor appetite, convulsions in calves, lameness in pigs, deformed front legs of rabbits, bowleggedness in calves, females unable to suckle their young, sterility in males, pale blood and pale skin color of cattle, sheep, and goats, thumps (anemia, difficult breathing) in pigs, pullorum in chicks, listlessness, retarded glandular activity, stunted growth and acetonemia in cattle, goats, and swine, pathogenic intestinal microflora in ruminants, multiple disorders, abortive troubles in ruminants, falling disease or heart failure, scours, soft and brittle bones, and swollen joints in animals; that the article was an adequate and effective treatment to correct livestock deficiencies of zinc; to cause cows to eat better, look better, milk better, breed better, and to make them healthier all around and easier to settle; to increase the milk supply of cows; to insure a higher butterfat content and a lower bacteria count in raw milk; to insure more and better calves; to eliminate the need for artificial help with afterbirth; to improve the breeding quality of bulls and the conception rate of cows; to prevent anemia; to have a synergistic effect as essential biocatalysts in the formation of enzymes, hemoglobin, proteins, hormones, etc., leading to disease resistance; and to change Bang's reactors to negative; that the article possessed antibacterial properties and thus constituted antibiotics [sic]; and that the article would be effective to improve lamb and sheep flocks, improve their appetites, and increase their weight and resistance to pneumonia and parasites, to cure unthrifty sheep and improve their growth,

to increase the weight and improve the coats of animals, to correct breeding troubles, and to improve the quality of the sperm of bulls. The article was not an adequate and effective treatment for such conditions, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: January 9, 1953. Default decree of condemnation and destruction.

3980. Misbranding of Vito. U. S. v. 400 Bags, etc. (F. D. C. No. 33325. Sample Nos. 1987-L, 1988-L.)

LIBEL FILED: July 2, 1952, Southern District of Florida.

ALLEGED SHIPMENT: On or about March 20, 1952, by Browar Products, Inc., from Elwell, Mich.

PRODUCT: 400 5-pound bags of *Vito* for turkeys, hogs, cattle, chickens, and other livestock, and 200 4-pound bags of *Vito* for dogs and cats at West Hollywood, Fla., together with a number of pamphlets entitled "Vito for Turkeys, Hogs, Cattle, Chickens, and Other Livestock" and "Vito for Dogs and Cats," a number of placards entitled "Vito for Dogs and Cats," and a number of copies of testimonial sheets.

LABEL, IN PART: (Bag) "Vito for Turkeys–Hogs Cattle–Chickens and Other Livestock * * * Contains—Calcium Carbonate not less than 20%, Sulphate of Iron, Phosphorous 3.5%, Sodium Chloride not more than 25%, Magnesium Sulphate, Specially Prepared Wood Ash, Baked Bone Meal," and "Vito for Dogs and Cats * * * Contains Calcium Carbonate not less than 20%, Phosphorous 3.5%, Sulphate of Iron, Sodium Chloride not more than 25%, Magnesium Sulphate, Specially Prepared Wood Ash, Baked Bone Meal."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned pamphlets, placards, and testimonial sheets were false and misleading since the articles were not effective in the prevention and treatment of the diseases and conditions represented and suggested and were not capable of fulfilling the other promises of benefit made for them. With respect to the *Vito* for turkeys, hogs, cattle, chickens, and other livestock the statements represented and suggested that the article was effective in the prevention and treatment of worms, rickets, parasitic attacks, neurotic [sic] enteritis, blackhead, coccidiosis, malnutrition, diarrhea, and scours in calves; that the article had tonic properties; that it would promote good health, good growth, and better offspring; that it would prevent parasites and keep animals in top condition; and that it would insure against many profit-robbing diseases. With respect to the *Vito* for dogs and cats, the statements represented and suggested that the article was effective in the prevention and treatment of worms and rickets; that the article would prevent running fits and rickets, promote good health, good growth, and healthy offspring, keep animals in top condition and dogs in sound health with sleek coats, promote appetite and cure lack of appetite due to worms, and promote husky litters and guard the health of the mother; and that the article would assure against worms, scours, parasitic and bacteriatic [sic] troubles, and act as a general health and body builder.

DISPOSITION: August 1, 1952. Default decree of forfeiture and destruction.

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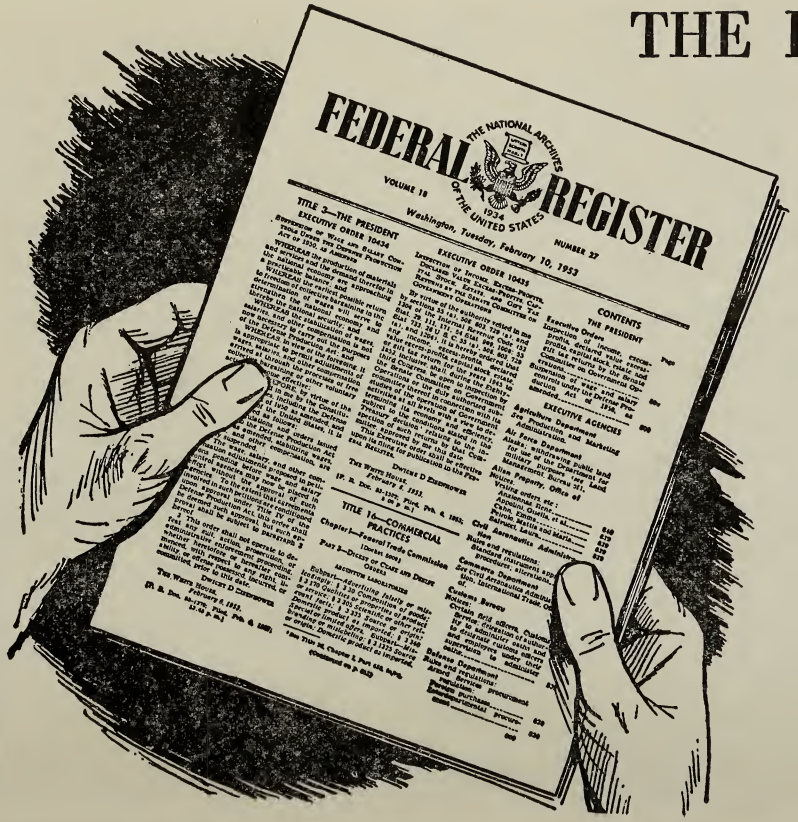
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U. S. GOVERNMENT PRINTING OFFICE: 1953





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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3981–4000

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

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CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *September 4, 1953.*

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DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3981. Misbranding of vaginal suppositories. U. S. v. 131 Boxes * * *. (F. D. C. No. 34396. Sample No. 39888–L.)

LIBEL FILED: December 24, 1952, Southern District of California.

ALLEGED SHIPMENT: On or about September 29, 1952, by the Dr. J. A. McGill Co., from Chicago, Ill.

PRODUCT: 131 boxes of *vaginal suppositories* at Los Angeles, Calif. Examination showed that the product contained approximately 47 percent ammonium alum and 10.6 percent borax in a fatty base. Each box contained a copy of a leaflet entitled "Dr. J. A. McGill Co.'s Suppositories."

LABEL, IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum – Borax – Petrolatum * * * Dr. J. A. McGill Co. * * * Chicago 16, Ill."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement appearing in the labeling of the article "For Simple Irritations Of The Vaginal Tract" was false and misleading. The statement represented and suggested that the article was an adequate and effective treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract, whereas the article was not an adequate and effective treatment for these diseases.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil at bedtime, insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

DISPOSITION: January 26, 1953. Default decree of condemnation and destruction.

3982. Misbranding of Mam-Zelle syringe and Mam-Zelle tablets. U. S. v. 11 Cartons, etc. (F. D. C. No. 34656. Sample No. 18577–L.)

LIBEL FILED: February 17, 1953, District of Arizona.

ALLEGED SHIPMENT: On or about November 29, 1952, by the Barclay Pharmaceutical Products Co., from Pasadena, Calif.

PRODUCT: 1 carton containing 12 12-tablet bottles of *Mam-Zelle tablets*, and 11 cartons, each containing 2 packages, and each package consisting of a cardboard box containing 1 *Mam-Zelle syringe* and 1 12-tablet bottle of *Mam-Zelle tablets*, at Phoenix, Ariz. There were enclosed in each package a circular designated "For women Strictly personal," and a circular designated "How To Use *Mam-Zelle* Effervescent Feminine Hygiene Syringe Unit."

The *Mam-Zelle syringe* consisted of a two-piece plastic cylinder which was closed except for a valve-operated exit tube which connected through a short piece of rubber tubing to a plastic nozzle having eight small holes at the sides and one small hole at its tip. In operation, the plastic cylinder was charged by filling with water and placing one of the *Mam-Zelle tablets* in position. After the assembling of the cylinder, the water and tablet were brought into contact whereby the effervescing-type tablet dissolved with the liberation of

carbon dioxide gas which created a pressure inside the cylinder. When the release valve was pressed, the liquid emerged under pressure from the cylinder and passed through the rubber tubing into the plastic nozzle whence it emerged in streams from the openings of the nozzle.

LABEL, IN PART: (Box) "Mam-Zelle Effervescent The New Way to Feminine Daintiness * * * Feminine Hygiene Syringe Unit. This package contains syringe and bottle of 12 Mam-Zelle tablets (Sodium Chloride & Boric Acid.) Use as directed in enclosed circular. Caution: Use only one tablet at a time."

NATURE OF CHARGE: Misbranding, Section 502 (j), the device and the tablets were dangerous to health when used in the dosage and with the frequency and duration recommended in the labeling since the applicator nozzle which was to be inserted into the vagina had an exit hole at its very tip, thus enabling part of the liquid to be directed into the cervical opening with harmful results, and because of the excessive pressure in the device, the emerging liquid was applied with sufficient force to cause damage to the genital tract.

DISPOSITION: March 24, 1953. The Barclay Pharmaceutical Products Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency. The devices were dismantled and rebuilt to correct the danger complained of.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

3983. Misbranding of diethylstilbestrol tablets, dextro-amphetamine sulfate tablets, methyltestosterone tablets, and conjugated estrogens (equine) tablets. U. S. v. Nathan A. Riemer (Riemer Pharmacy), and Sidney Koach. Pleas of nolo contendere. Fines of $250 against Defendant Riemer and $50 against Defendant Koach. (F. D. C. No. 34311. Sample Nos. 35931–L, 35934–L, 36203–L, 36228–L.)

INFORMATION FILED: February 9, 1953, Northern District of Ohio, against Nathan A. Riemer, trading as Riemer Pharmacy, Cleveland, Ohio, and Sidney Koach, an employee of the pharmacy.

NATURE OF CHARGE: On or about May 16 and 24 and June 10 and 11, 1952, while a number of *diethylstilbestrol tablets*, *dextro-amphetamine sulfate tablets*, *methyltestosterone tablets*, and *conjugated estrogens (equine) tablets* were being held for sale at the Riemer Pharmacy, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the drugs so dispensed being misbranded.

Nathan A. Riemer was charged with causing the act of dispensing in each of the four counts of the information, and Sidney Koach was joined as a defendant in one of the counts.

DISPOSITION: March 2, 1953. Pleas of nolo contendere having been entered by the defendants, the court fined Defendant Riemer $250 and Defendant Koach $50.

3984. Misbranding of Sulfonamides Triplex tablets and sulfathiazole tablets. U. S. v. William A. Walker (Fourth Street Drug Store and Palace Drug Store), and Aaron E. Henry and Frank H. Hudson, Jr. Pleas of nolo contendere. Fine of $50 against each defendant. (F. D. C. No. 34303. Sample Nos. 46515–L to 46517–L, incl., 46524–L to 46526–L, incl.)

INFORMATION FILED: On or about January 2, 1953, Northern District of Mississippi, against William A. Walker, trading as the Fourth Street Drug Store and the Palace Drug Store, Clarksdale, Miss., and against Aaron E. Henry, pharmacist and manager of the Fourth Street Drug Store, and Frank H. Hudson, Jr., a pharmacist of the Palace Drug Store.

NATURE OF CHARGE: On or about June 18, 19, and 20, 1952, while a number of *Sulfonamides Triplex tablets* and *sulfathiazole tablets* were being held for sale at the Fourth Street Drug Store and a number of *sulfathiazole tablets* were being held for sale at the Palace Drug Store, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. William A. Walker was charged with causing the act of dispensing in each of the six counts of the information, Frank H. Hudson, Jr., was joined as a defendant in two of the counts, and Aaron E. Henry was joined as a defendant in one count. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drugs being misbranded.

DISPOSITION: March 25, 1953. Pleas of nolo contendere having been entered by each of the defendants, the court fined each defendant $50.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

3985. Adulteration and misbranding of first aid kits. U. S. v. 58 First Aid Kits * * *. (F. D. C. No. 34093. Sample No. 14049–L.)

LIBEL FILED: November 5, 1952, District of Colorado.

ALLEGED SHIPMENT: On or about September 5, 1952, by Industrial Drug Supplies, Inc., from New York, N. Y.

PRODUCT: 58 *first aid kits*, one of the components of which consisted of a box containing 24 *sulfadiazine tablets* in a cellophane envelope, at Denver, Colo. Analysis showed that the *sulfadiazine tablets* contained approximately ½ gram of sulfadiazine.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the *sulfadiazine tablets* differed from that which they were represented to possess, namely, 1.0 gram of sulfadiazine per tablet.

Misbranding, Section 502 (a), the label statement "Sulfadiazine Tablets 1.0 Gm." was false and misleading as applied to tablets containing ½ gram of sulfadiazine, and the label statement "take the contents of one envelope (4 tablets)" was false and misleading since the one envelope in the box contained 24 tablets. Further misbranding, Section 503 (b) (4), the tablets were a drug intended for use by man which, because of toxicity and other potentiality for harmful effect and method of use and the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer the drug, and the label of the tablets failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: January 2, 1953. Default decree of condemnation. The court ordered that the *sulfadiazine tablets* be removed from the first aid kits and be destroyed and that the first aid kits be delivered to a Federal institution.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3986. Misbranding of Cellaids. U. S. v. 100 Packages, etc. (F. D. C. No. 34157. Sample Nos. 40669–L, 41251–L to 41253–L, incl., 41255–L to 41257–L, incl., 41259–L to 41262–L, incl., 41264–L.)

LIBEL FILED: On or about December 2, 1952, Western District of Washington.

ALLEGED SHIPMENT: On various dates between March 1 and September 1, 1952, by George Collingwood, from Denver, Colo., and Long Beach, Calif.

PRODUCT: 100 packages of assorted drugs at Seattle, Wash. These drugs were designated generally as *Cellaids* and consisted of individual items labeled as described below. The drugs were accompanied by labeling consisting of leaflets entitled "Bio-Chemistry" and "A Few Facts Worth Knowing" and books entitled "The Study of Bio-Chemistry Fourth Edition by George Collingwood, D. C., N. D., B. C. D. Denver, Colorado" and "Bio-Chemistry or the Business of Living * * * by George H. Collingwood, B. C., N. D., D. C. * * * Denver, Colorado."

LABEL, IN PART: (Packages) "Cellaids * * * George Collingwood, D. C., N. D. Denver"; (individual items) "Homeopathic Product Potassium Phosphate * * * No. 6," "Calcium Fluoride * * * No. 1 * * * 12–X," [or "Calcium Phosphate * * * No. 2 * * * 6–X," "Calcium Sulphate * * * No. 3 * * * 6–X," "Potassium Chloride No. 5 * * * 6–X," "Potassium Sulphate * * * No. 7 * * * 6–X," "Sodium Chloride * * * No. 9 * * * 6–X," "Sodium Phosphate * * * No. 10 * * * 6–X," "Sodium Sulphate * * * No. 11 * * * 6–X," "Silicea Silica No. 12 * * * 12–X"] * * * Homeopathic Product" and "Bioplasma Ratio of 9 to 1 6–X * * * Combination of the following twelve minerals homeopathically prepared * * * Equal parts of each: Calcium Phosphate Potassium Chlorid Calcium Fluorid Potassium Phosphate Calcium Sulfate Potassium Sulfate Iron Phosphate Sodium Chlorid Magnesium Phosphate Sodium Phosphate Silica Sodium Sulfate (Added 50 units Vitamin B_1 to each tablet)."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets and books accompanying the articles were false and misleading since the articles were not an adequate and effective preventive and treatment for the conditions and purposes stated and implied and were not capable of fulfilling the promises of benefit made for them. The statements represented and suggested:

That the *calcium fluoride* was an adequate and effective treatment for soft flabby muscles, broken-down elastic fiber, enlarged heart, heart leakage, floating kidney, rupture, appendicitis, varicose veins, tumors, hardening of the arteries, hard knots on the mother's breast, hard tumors, high blood pressure, abscess, asthma, tired back, inability of the uterus to expel the fetus, corns, bunions, all hard and soft swellings, cough, diphtheria, gout, hard or soft glands, piles, pus, syphilis, diseased spine, vein enlargements, paralysis, and bladder and kidney stones;

That the *calcium phosphate* was an adequate and effective treatment for all chronic conditions of the human body, Bright's disease, consumption or TB, catarrh, anemia, asthma, brittleness of the bones, brainfag, scanty and salty milk, cancer, cataract, cholera infantum, weakness before and after childbirth, chronic diseases of all kinds, weariness, night sweats, epilepsy, gallstones, heart disease, paralysis, rheumatism, rickets, St. Vitus' dance, decayed teeth, toothache, typhoid, ulcers, whooping cough, yellow fever, and male and female disorders;

That the *calcium sulfate* was an adequate and effective treatment for cleansing the body, boils, carbuncles, abscesses, pimples, all pus conditions of the surface, inflamed bladder, pus in the urine, burns, colds, chickenpox, consumption, gonorrhea, gumboil, weakness of the liver and sickness of the stomach, sore throat, syphilis, ulcerated teeth, tonsillitis, ulcers that are not deep seated, tubercular ulcers of the lungs, rheumatism, and cramps;

That the *potassium chloride* was an adequate and effective treatment for tonsillitis, scarlet fever, smallpox, measles, chickenpox, scalds, swollen conditions, chronic diseases in growing children, abscess, chilblains, Bright's disease, bronchitis, catarrh, croup, diabetes, epilepsy, diptheria, any swollen gland, mumps, goiter, gonorrhea, injuries, bruises, cuts, burns, pains in the liver, meningitis, pleurisy, pneumonia, shingles, syphilis, whooping cough, yellow fever, and common sore throat;

That the *potassium phosphate* was an adequate and effective treatment for deficient brain power, nervousness, lack of energy, paralysis, palpitation of the heart, sleeplessness, insanity, abscess, anemia, asthma, blood poisoning of all types where there is gangrene, Bright's disease, depression, irritability, brainfag, diphtheria, dizziness, epilepsy, fever, sluggish pulse, irregular palpitations, sinking spells, hemorrhage, hoarseness, hysteria, bronchitis, loss of voice, sciatica, sleeplessness, spasms due to fright, spinal weakness caused by disease, syphilis, chancre, typhoid, wasting conditions, and whooping cough;

That the *potassium sulfate* was an adequate and effective preventive and treatment for clogging of the pores, hot, dry, and feverish condition, abscess, bronchitis, cancer, chickenpox, colds, colic, consumption, erysipelas, gonorrhea, gleet, hoarseness, influenza, measles, pneumonia, scarlet fever, all skin diseases, smallpox, indigestion, syphilis, yellow fever, and to tone up the nerves;

That the *sodium chloride* was an adequate and effective treatment for dropsy, languidness, drowsiness, tearfulness, sadness, chilliness, hay fever, sunstroke, fresh colds, sneezing, anemia, green sickness, atrophy, bed-wetting, bites or insect stings, excessive urination, dry or watery constipation, brain and mental conditions, blues, wandering of the mind, stupor, sleepiness, melancholy, hopelessness, dejected spirits, gloomy thoughts, weariness, exhaustion, cancer, tumors, catarrh, chickenpox, colds, consumption, delirium, dropsy, fevers, gonorrhea, hay fever, hiccup, lockjaw, lumbago, bronchitis, mumps, stiff neck, shingles, indigestion, sunstroke, sweats, vomiting, and whooping cough;

That the *sodium phosphate* was an adequate and effective preventive and treatment for jaundice, colic, bilious headache, gout, acute and chronic rheumatism, acid conditions, backache, cancer on the tongue, colic, cholera infantum, diabetes, diarrhea, dizziness, epilepsy, erysipelas, fevers, goiter, rheumatism, worms of any kind, pains, discharges, profuse and sour-smelling perspiration, and a coated tongue;

That the *sodium sulfate* was an adequate and effective treatment for cholera, chills, fever and ague, la grippe, jaundice condition, yellow eyeballs, abscess, asthma, backache, bronchitis, catarrh, colic, consumption, diabetes, diarrhea, diphtheria, dizziness, erysipelas, flu or la grippe, jaundice, ringworm, typhoid, and yellow fever;

That the *silica* was an adequate and effective treatment for the removal of pus and waste accumulations, to ripen boils, abscesses, and carbuncles, and for anemia, asthma, organs of the body that are shrunken or wasting away, brain worry, consumption, constipation, felons, foul breath, locomotor ataxia, syphilis, and ulcers, and to prevent disease.

Further misbranding, Section 502 (a), the following statements in the leaflets and books accompanying the *Bioplasma* were false and misleading since this article was not capable of fulfilling the promises of benefit made for it: "covers every known disease found in the human organism," "aids in purifying the blood and supplying the elements of which the cells, tissue, bone and nerve are composed," "When the body is in a run-down condition," "Proper minerals as listed in this pamphlet in their proper heads, and for the specific symptoms, either alone, or in combination with proper foods, can overcome nearly all bodily ailments," and "Bio-Plasma * * * containing all 12 minerals * * * Bio-Plasma Plain, containing all 12 minerals." Further misbranding, Section 502 (a), the statement on the package label, "A general tonic" was false and misleading since the article did not possess tonic properties.

Further misbranding, Section 502 (f) (1), the labeling of the following articles failed to bear adequate directions for use for the following conditions and purposes for which they were offered in a lecture given by George Collingwood at Seattle, Wash., on October 11, 1952: *Calcium fluoride*—for enlarged heart; *calcium phosphate*—to build albumin; *calcium sulfate*—to build connective tissue of the bone, to hold together holes in bones; *potassium chloride*—for appendicitis, floating kidney; to build tissue; to control all swollen conditions, wounds, and injuries; *potassium phosphate*—to give one thinking power; to create gray matter in the nerve ends and the brain; *potassium sulfate*—to create oils in the body; open the pores of the skin; enable the skin to breathe; and for fever; *sodium chloride*—to attract water in order to bathe the cells throughout the body; *sodium phosphate*—to balance and control acids in the body; *sodium sulfate*—to control the bile and pancreas for the treatment of flu or virus X and coryza; to take care of the liver and keep it in line, and in conditions where there is yellow in the eyeballs, yellow jaundice, yellow fever, or any yellow conditions; for fever, ague, and shaking; and *silicea silica*—to build the skin; for cysts, carbuncles, and boils.

The products were misbranded under Section 502 (a), as described above, when introduced into and while in interstate commerce, and they were further misbranded under Section 502 (f) (1), as described above, while held for sale after shipment in interstate commerce.

DISPOSITION: April 3, 1953. Default decree of condemnation and destruction.

3987. Misbranding of Gallusin and Kloronol. U. S. v. 10 Boxes, etc. (F. D. C. No. 34590. Sample Nos. 59217–L, 59218–L.)

LIBEL FILED: January 7, 1953, Western District of North Carolina.

ALLEGED SHIPMENT: On or about October 17, 1952, by the Sumlar Co., from Brooklyn, N. Y.

PRODUCT: 10 100-tablet bottles of *Gallusin* and 22 1-ounce bottles of *Kloronol* at Charlotte, N. C.

LABEL, IN PART: (Box) "Gallusin Eminent Formula For The Temporary Relief of Occasional Constipation Contains Extracts of Ox Bile, Nux Vomica 1/16 gr. (Strychnine .0046 gr.), Cascara Sagrada and Phenophthalein as Active Ingredients with Papain and Oleoresin of Capsicum * * * Distributed by Sumlar Co., 2700 Church Ave., Brooklyn 26, N. Y."

(Bottle) "Kloronol A Famous Formula For Application To Nasal Areas Contains alcohol 2%, chlorbutanol 0.5% (chloroform derivative), ephedrine sulfate, epinephrine hydrochloride potassium bicarbonate, borax, thymol, eucalyptol, and methyl salicylate. Distributed by Sumlar Co. 2700 Church Ave. Brooklyn 26, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, (Gallusin) to curb misery due to lack of healthy bile, relieve gallbladder sufferers lacking healthy bile, to effect remarkable results in sufferers with agonizing colic, stomach, and gallbladder misery due to lack of healthy bile, and to exert amazing power to stimulate flow of healthy bile, and (Kloronol) for the adequate and effective treatment of sinus affections, catarrh, sinus headaches, and earache, which were the symptoms and conditions for which the articles were offered in the November 20 and 27, 1952, issues of a newspaper of general circulation, in the Charlotte, N. C., area, and which advertisements were disseminated and sponsored by and on behalf of the manufacturer, packer, and distributor of the articles. The articles were misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: February 25, 1953. Default decree of condemnation and destruction.

3988. Misbranding of Sanitas herb tea. U. S. v. 6 Pounds, etc. (F. D. C. No. 34133. Sample Nos. 54585–L, 54586–L.)

LIBEL FILED: November 19, 1952, Northern District of Illinois.

ALLEGED SHIPMENT: On or about March 11 and May 26, 1952, from New York, N. Y.

PRODUCT: 6 pounds in bulk and 63 boxes of *Sanitas Herb Tea No. 88* and 75 pounds in bulk and 100 boxes of *Sanitas Herb Tea No. 101* at Chicago, Ill., in the possession of the Sanitas Herb Tea Co., together with 2,000 leaflets printed in English, 2,000 leaflets printed in Polish, and 2,000 leaflets printed in Lithuanian, entitled "Keep Well With Sanitas Herbs Nature Is The Best Guide."

RESULTS OF INVESTIGATION: The boxes of the articles had been repackaged by the consignee from the bulk lots of the articles. The above-mentioned leaflets were printed for the consignee and were distributed to customers purchasing the articles.

LABEL, IN PART: "Sanitas Formula No. 88 Active Ingredients: Cascara Bark, Comfrey Root, Marshmallow Root and Flaxseed" and "Sanitas Herb Tea No. 101 Active Ingredients: Senna Leaves."

NATURE OF CHARGE: Misbranding, Section 502(a), the following statements on the box labels and in the above-mentioned leaflets were false and misleading since the articles were not capable of fulfilling the promises of benefit made for them and were not effective in the treatment of the conditions

stated and implied: (box label—*Sanitas Herb Tea No. 88*) "Hepatic Alterative," (box label—*Sanitas Herb Tea No. 101*) "Kidney and Bladder Sickness," and (leaflet) "For Your Inner Well-Being and Outer Good Looks Sanitas Herb Tea No. 88, for Liver and Gall Bladder complaints * * * it has often eliminated pain and liver spots * * * Are Your Kidney Tubes and Filters In Working Order? * * * If you have an excess of acids in your blood stream, your kidney tubes may be overworked * * * What happens when kidney disorders permit poisonous matter to remain in your blood? Then you are ill indeed! Then you may suffer with rheumatic pains, backache, loss of pep or energy, getting up nights, swelling puffiness under the eyes, headaches, dizziness, frequent or scanty passage, with smarting and burning at times. Sanitas No. 101 To The Rescue! Here is where Sanitas Herb Tea No. 101—for Kidney and Bladder Afflictions—comes to your rescue. Kidney trouble has caused untold human suffering but No. 101 has done more than its share in alleviating this form of human misery. Like the knight in shining armor who slew the dragon, No. 101 proceeds to slay the dragon of painful kidney and bladder trouble. Your backache, leg pain, broken sleep, painful passages depart in a hurry from the field of battle. Sanitas No. 101 does that for you—try it—and then see how it soothes the bladder and stimulates kidney action."

Further misbranding, Section 502 (f) (2), the labeling of the articles in the boxes failed to bear such adequate warnings against unsafe duration of administration, in such manner and form, as are necessary for the protection of users since the labeling failed to bear a warning to the effect that frequent or continued use of the articles, or their use three times daily as directed in the labeling on the boxes, may result in the dependence upon laxatives to move the bowels.

The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: January 29, 1953. Default decree of condemnation and destruction.

3989. Misbranding of Colusa ointment. U. S. v. 17 Jars * * *. (F. D. C. No. 34416. Sample No. 14548–L.)

LIBEL FILED: December 18, 1952, District of Colorado.

ALLEGED SHIPMENT: On or about October 9, 1952, by the J & J Remedy Co., from Los Angeles, Calif.

PRODUCT: 17 jars of *Colusa ointment* at Denver, Colo.

LABEL, IN PART: (Jar) "Colusa Ointment * * * Net Contents 3 Oz. $3.00 * * * Active Ingredients Zinc Oxide, Benzocain, Menthol, Camphor, Lanolin, Yellow Bees Wax, 1/10 of 1% Phenol (carbolic acid crystals) in an Unrefined Petroleum oil base."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "for relief of Piles and Hemorrhoids" was false and misleading since the article was not an effective treatment for piles and hemorrhoids.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, for skin troubles generally and for eczema, scabies, athlete's foot, and rash, which were the conditions for which the article was offered in advertising sponsored by or on behalf of the shipper.

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DISPOSITION: February 11, 1953. Default decree of condemnation. The court ordered that a portion of the product be delivered to the Federal Security Agency and that the remainder be destroyed.

3990. Misbranding of Color-Therm device. U. S. v. 1 Device * * *. (F. D. C. No. 34398. Sample No. 43845–L.)

LIBEL FILED: December 8, 1952, Western District of Oklahoma.

ALLEGED SHIPMENT: Prior to December 8, 1952, from Mission, Kans., by E. K. Kusch, who had rented or purchased the device from Fred Gerkey.

PRODUCT: One *Color-Therm device* at Fairview, Okla. The device consisted of a unit with six U-shaped tubes and a hand applicator with one straight and two U-shaped tubes for producing colored lights, similar to the so-called neon lights, with electrical connections to operate them.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use for the purposes for which it was intended, namely, liver trouble, ulcers, high blood pressure, and other diseases.

DISPOSITION: February 3, 1953. Default decree of condemnation. The court ordered that the device be delivered to the Food and Drug Administration.

3991. Misbranding of Color-Therm device. U. S. v. 1 Device * * *. (F. D. C. No. 34401. Sample No. 16497–L.)

LIBEL FILED: On or about December 11, 1952, Northern District of Oklahoma.

ALLEGED SHIPMENT: On or about January 21, 1952, by Fred Gerkey, from Mission, Kans.

PRODUCT: One *Color-Therm device* at Sapulpa, Okla. The device consisted of a unit with six U-shaped tubes and a hand applicator with one straight and two U-shaped tubes for producing colored lights, similar to the so-called neon lights, with electrical connections to operate them.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use for the purposes for which it was intended, namely, arthritis, rheumatism, and other diseases.

DISPOSITION: December 31, 1952. Default decree of condemnation. The court ordered that the device be dismantled and that any parts of use in the commercial field be sold.

3992. Misbranding of ultrasonic device. U. S. v. 1 Device * * *. (F. D. C. No. 34468. Sample No. 62314–L.)

LIBEL FILED: January 6, 1953, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about October 14, 1952, by the Porter Co., from Mt. Vernon, Ill.

PRODUCT: One *ultrasonic device* at Potosi, Mo., together with a booklet designated as "Porter Ultrasonics Treatment Chart." The device was classed as an ultrasonic vibrator since it gave off mechanical vibrations at a frequency far above the range of audible sound.

LABEL, IN PART: (Device) "The Porter Co. Mt. Vernon, Ill. Model 4 Serial 104."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklet accompanying the device were false and misleading. The statements represented and suggested that the device would provide an adequate and effective treatment for abscesses, adnexitis, angina pectoris, arthritis, asthma,

Bechterew's disease, bed-wetting, bronchitis (bronchiectasis), Buerger's disease, bursitis, causalgia, colecystitis, colesystopathic, coccygodynia, colitis, coxarthrosis, diphtheric bacilli carriers, glands (tumefaction) Dupuytren's contraction, dysbasia, elephantiasis, eczema, endangitis obliterans, epicondylitis, epilepsy, erythema nodosa, erythromelalgia, fistula, furuncle, carbuncle, joint effusion, gingivitis, urethral stricture, skin carcinoma, hemiplagia, herpes zoster, hypertonia essential, infiltrations, intercostal neuralgia, induratic penis plast, ischialgia, lockjaw, lumbago, lymphadenitis, mastitis, Meniere's disease, multiplesclerosis, myalgia, myelitis, scar contraction, neuralgia and neuritis, neuroma after amputation, osteomyelitis, ostitis and periostitis, panaris, paradentosis, parotitis, paronychia, parulis, periarthritis, phlegmon, polyarthritis, postoperative pain, prostatitis, pruritus, pulpitis, Raynaud's disease, rheumatism, X-ray ulcers, scalenus syndrom, sweat glands abscess, scleroderma, sinusitis, spondylosis, sudek'sche dystrophy, tendovaginitis, thrombophlebitis, tonsillitis, trieminus neuralgia, tuberculosis, tumors, ulcus cruris, ulcus ventrical and duodenal, warts, dental granuloma, cellulitis, radiculitis, kieferhoehlenetzueundung, and nebenhoehlenetzuendung. The device would not provide an adequate and effective treatment for such conditions.

Further misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: February 4, 1953. Default decree of condemnation. The court ordered that the device be delivered to the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS *

3993. Adulteration and misbranding of vitamin B complex capsules. U. S. v. 2 Bottles, etc. (and 1 other seizure action). (F. D. C. Nos. 34521, 34538. Sample Nos. 56839–L, 56841–L, 56842–L.)

LIBELS FILED: January 2 and 7, 1953, Northern District of Ohio.

ALLEGED SHIPMENT: Between the approximate dates of August 8 and December 8, 1952, by Fellows Medical Mfg. Co., Inc., from New York, N. Y.

PRODUCT: 2 1,000-capsule bottles and 161 50-capsule bottles of *vitamin B complex capsules* at Cleveland, Ohio.

LABEL, IN PART: "Fellows Vitamin B-Complex Capsules."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 10 milligrams of thiamine hydrochloride (vitamin B_1) per capsule.

Misbranding, Section 502 (a), the label statement "each capsule contains Thiamine Hydrochloride (10 M. D. R.) 10 Mg." was false and misleading as applied to the article, which contained less than that amount of thiamine hydrochloride (vitamin B_1) per capsule.

DISPOSITION: February 18, 1953. Default decrees of condemnation and destruction.

3994. Adulteration and misbranding of vitamin B complex capsules. U. S. v. 1 Bottle, etc. (F. D. C. No. 34537. Sample No. 56840–L.)

LIBEL FILED: January 7, 1953, Northern District of Ohio.

*See also No. 3985.

ALLEGED SHIPMENT: On or about October 6 and 20 and December 8, 1952, by Fellows Medical Mfg. Co., Inc., from New York, N. Y.

PRODUCT: 1 1,000-capsule bottle and 55 50-capsule bottles of *vitamin B complex capsules* at Cleveland, Ohio.

LABEL, IN PART: "Fellows Vitamin B-Complex Capsules each capsule contains Thiamine Hydrochloride (10 M. D. R.) 10 Mg. * * * Therapeutic."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 10 milligrams of thiamine hydrochloride (vitamin B_1) per capsule.

Misbranding, Section 502 (a), the label statement "each capsule contains Thiamine Hydrochloride (10 M. D. R.) 10 Mg." was false and misleading as applied to the article, which contained less than that amount of thiamine hydrochloride (vitamin B_1) per capsule.

DISPOSITION: February 18, 1953. Default decree of condemnation and destruction.

3995. Adulteration and misbranding of isopropyl alcohol rubbing compound. U. S. v. 200 Cases * * *. (F. D. C. No. 34459. Sample No. 44824-L.)

LIBEL FILED: December 23, 1952, District of Connecticut.

ALLEGED SHIPMENT: On or about October 29 and November 13, 1952, by S. T. Brill Co., Inc., from Brooklyn, N. Y.

PRODUCT: 200 cases, each containing 12 16-ounce bottles, of *isopropyl alcohol rubbing compound* at New Haven, Conn. Examination showed that the product contained 63.6 percent isopropyl alcohol.

LABEL, IN PART: (Bottle) "Clifton Isopropyl Alcohol Rubbing Compound."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, "Isopropyl Alcohol Rubbing Compound," the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium since it contained less than 68 percent isopropyl alcohol.

Misbranding, Section 502 (a), the label statement "Isopropyl Alcohol 70% By Volume" was false and misleading as applied to the product, which contained less than 70 percent isopropyl alcohol.

DISPOSITION: February 13, 1953. S. T. Brill Co., Inc., Brooklyn, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for reprocessing under the supervision of the Federal Security Agency.

3996. Adulteration and misbranding of adhesive strips. U. S. v. 60 Cartons * * *. (F. D. C. No. 34624. Sample No. 57478-L.)

LIBEL FILED: On or about January 27, 1953, District of Maryland.

ALLEGED SHIPMENT: On or about December 17, 1952, by the Sanette Mfg. Co., from New Rochelle, N. Y.

PRODUCT: 60 cartons, each containing 12 packages, of *adhesive strips* at Baltimore, Md.

LABEL, IN PART: (Retail package unit) "Sanette 12 Sterilized Waterproof Adhesive Strips."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be a drug, "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"],"

the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since the standard provides that "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]" must be sterile, whereas the article was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading.

DISPOSITION: February 20, 1953. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3997. Misbranding of Panrein tablets, Panbile tablets, Ioaquasol tablets, Noodor tablets, Nokof tablets, and Thiekla. U. S. v. 3 Bottles, etc. (F. D. C. No. 34651. Sample Nos. 46652–L to 46655–L, incl., 46657–L, 46658–L.)

LIBEL FILED: February 9, 1953, Southern District of Texas.

ALLEGED SHIPMENT: On various dates during the latter part of 1952 and the early part of 1953, by John C. Thie (TPCS Distributors), from Pasadena, Calif.

PRODUCT: 3 90-tablet bottles of *Panrein tablets*, 3 90-tablet bottles of *Panbile tablets*, 4 90-tablet bottles of *Ioaquasol tablets*, 3 90-tablet bottles of *Noodor tablets*, 2 40-tablet bottles of *Nokof tablets*, and 4 2-ounce jars of *Thiekla* at Houston, Tex., together wtih an accompanying booklet entitled "A New Approach to Therapy [Anat]."

LABEL, IN PART: (Bottle) "Formula I Panrein 90 tablets (1–wv) Each Tablet Contains: Barosma 65.0 Mg. Bear Berry 64.4 Mg. Couch Grass 66.2 Mg. Alfalfa 63.6 Mg. In a base of parsley and other inert filler," "Formula III Panbile 90 Tablets (3–WW) Each Enteric coated tablet contains: Pancreatin USP 259.2 Mg. Bile Salts (Ext. Ox Bile) 129.6 Mg. Dehydrocholic Acid 21.6 Mg. In desiccated protein and other excipients," "Formula 2 Ioaquasol 90 Tablets (2 WV) Each enteric coated tablet contains: Iodine 30.2 mg. Combined and proportioned by a special process making a water soluble iodine compound—Ioaquasol," "Formula XVII Noodor 90 Tablets (17–2W) Each tablet contains excipients and Chlorophyll which are completely water soluble," "Formula XXV Nokof 40 Tablets (25–W) Each tablet Contains: P. E. Licorice Root 32 mg., ester of Para-Amino-Benzoic acid 12 mg. (one of the Vitamin B Complex Factors); in a base containing Peppermint (ext.), Anise, and excipients," and (jar) "Formula V Thiekla (5–W) Contains: Oxides, Chlorides, Sulphates, Nitrates, and Carbonates, of Ca, Fe, Mg, Na, K, H, N, I, and other Colloidal minerals normally found in the human body."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklet were false and misleading since the articles were not adequate and effective treatments for the conditions and purposes represented and suggested. The statements represented and suggested:

That the *Panrein tablets* were an adequate and effective treatment for improving health, stopping the death process, maintaining normal health, dropsy, inflamed condition of the urinary organs, nervousness, irritable bladder, cystitis, diseases of the urinary tract, gravel, chronic catarrh of the bladder, morbid irritation of the bladder and urethra, diseases of the prostate, urinary

*See also Nos. 3981, 3985, 3986, 3988, 3989, 3992–3996.

incontinence, kidney complaint, chronic nephritis, ulceration of the urinary organs, bladder catarrh, gleet, leucorrhea, menorrhagia, and uremic poisoning;

That the *Panbile tablets* were an adequate and effective treatment for digestive disorders, maintaining normal health, enabling one to be more refreshed with less sleep, and causing one to feel better generally;

That the *Ioaquasol tablets* were an adequate and effective treatment for maintaining normal health, normalizing the metabolism, providing "pick-up," "looked-for-relief," and "lift," coarse nails, rough, dry, and scaly skin, skin eruptions, sterility, lowered physical energy, impaired mental faculties, irritability, nervousness, rapid pulse, irregular pulse, poor digestion, decreased liver function, emaciation, obesity, myxedema, increased tendency to infection, inhibited development of children, low basal metabolism rate, sudden gain or loss of weight, serous accumulation, skin rash, bronchial cough, eye dryness, improper functioning of the glands, especially the thyroid, excessive mucus secretions, enlargement of the glands such as the prostate, difficult respiration, nerve pressure, tendency to malignancy, toxicity, cell exhaustion, arthritis, rheumatism, asthma, allergies, angioneurotic edema, arteriosclerosis, maternal deficiencies causing stillbirth, reduced flow of endosecretions, low icterus index, fungus infections, trichomonas vaginitis, ringworm, malnutrition, acute infectious diseases, fevers, glandular enlargement, chronic colds, eczema, and rheumatic fever;

That the *Noodor tablets* were an adequate and effective treatment for stimulating contractility of heart tissue, preserving heart tissue, dilating small arteries, increasing respiratory volume, decreasing the effect of fatigue of nerve and muscle tissues, increasing nitrogen metabolism, increasing hemoglobin and number of erythrocytes, increasing polymorphonuclear leucocytes, and increasing effectiveness of hormone and glandular extracts;

That the *Nokof tablets* were an adequate and effective treatment for gastric ulcers, sore throat, laryngitis, and bronchitis;

That the *Thiekla* was an adequate and effective treatment for internal pollution, congestions, growths, pus accumulations, local and internal infections, internal conditions which fail to respond to any other therapy, toxic substances, sores, pains of the chest and stomach, headaches, intestinal cramps, weakness of the back, lumbago, spinal weakness, inflammations, red blotches, small sores, red nose, palpitations of the heart, ulcers, and sprains.

Further misbranding, Section 502 (e) (2), the *Nokof tablets* contained benzocaine, and the label failed to bear the common or usual name of the active ingredient.

The libel also alleged that another product was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: March 27, 1953. Default decree of condemnation and destruction.

3998. **Misbranding of mineral water. U. S. v. 26 Cases, etc.** (F. D. C. No. 34594. Sample No. 57463–L.)

LIBEL FILED: On or about January 8, 1953, District of Maryland.

ALLEGED SHIPMENT: On or about November 12, 1952, by Crownhill Laboratories, from Wyoming, Pa.

PRODUCT: 26 cases, each containing 12 1-quart bottles, of *mineral water* at Baltimore, Md., together with a number of circulars entitled "Here—Read Them for Yourself."

Examination showed that the product was water containing a small amount of suspended material and no significant amounts of calcium bicarbonate, calcium sulfate, magnesium chloride, or silica.

LABEL, IN PART: (Bottle) "Crownhill Farms Mineral Water."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements "Mineral Water with Mineral Added * * * Calcium Bicarbonate, Calcium Sulfate, Magnesium Chloride * * * Silica" appearing on the bottle label were false and misleading since the article contained nutritionally and therapeutically insignificant amounts of minerals and the compounds stated.

Further misbranding, Section 502 (a), certain statements in the above-mentioned circulars accompanying the article were false and misleading. The statements represented and suggested that the article, when used as directed, was effective in the treatment of arthritis, rheumatism, headaches, pains in joints, rheumatic fever, kidney trouble, and ailments of the stomach. The article, when used as directed, was not effective in the treatment of such conditions.

DISPOSITION: January 30, 1953. Default decree of condemnation and destruction.

3999. Misbranding of first aid kits. U. S. v. 23 Kits * * *. (F. D. C. No. 34448. Sample No. 69255-L.)

LIBEL FILED: December 24, 1952, District of Colorado.

ALLEGED SHIPMENT: November 12, 1952, by the E. D. Bullard Co., from San Francisco, Calif.

PRODUCT: 23 *first aid kits* in roll-up canvas containers, some of which contained a bottle of oil, at Denver, Colo.

LABEL, IN PART: (Bottle) "Mult Aply Oil O Sol An Inhibitory Antiseptic For Use As a Wet Dressing Contents 3½ cc. * * * C. A. Mosso Company Chicago, Illinois."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement on the bottle label "An Inhibitory Antiseptic For Use As A Wet Dressing" was false and misleading as applied to the article, which was not an antiseptic and would not act as an antiseptic wet dressing.

Further misbranding, Section 502 (e) (2), the component of the article, namely, "Mult Aply Oil," was a drug which was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

DISPOSITION: February 5, 1953. Default decree of condemnation. The court ordered that the bottles of "Mult Aply Oil" be destroyed and that the remainder of the first aid kits be delivered to a Federal institution for its use and not for sale.

DRUG ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH PACKAGING REQUIREMENTS OF AN OFFICIAL COMPENDIUM

4000. Misbranding of solution of citrate of magnesia. U. S. v. 7 Cases * * *. (F. D. C. No. 34644. Sample No. 26241-L.)

LIBEL FILED: February 3, 1953, District of Delaware.

ALLEGED SHIPMENT: On or about November 17, 1952, by the Integrity Magnesia Co., from Philadelphia, Pa.

PRODUCT: 7 cases, each containing 24 11 ½-ounce bottles, of *solution of citrate of magnesia* at Wilmington, Del.

LABEL, IN PART: (Bottle) "Blue Cross Brand * * * Effervescing Solution of Citrate of Magnesia U. S. P."

NATURE OF CHARGE: Misbranding, Section 502 (g), the article purported to be and was represented as "Magnesium Citrate Solution," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the article was not labeled as prescribed in such compendium since it contained benzoic acid, a preservative, and the presence and proportion of such preservative was not plainly stated on the label, as required by the compendium.

DISPOSITION: February 24, 1953. A default decree was entered providing for the delivery of the product to a local hospital.

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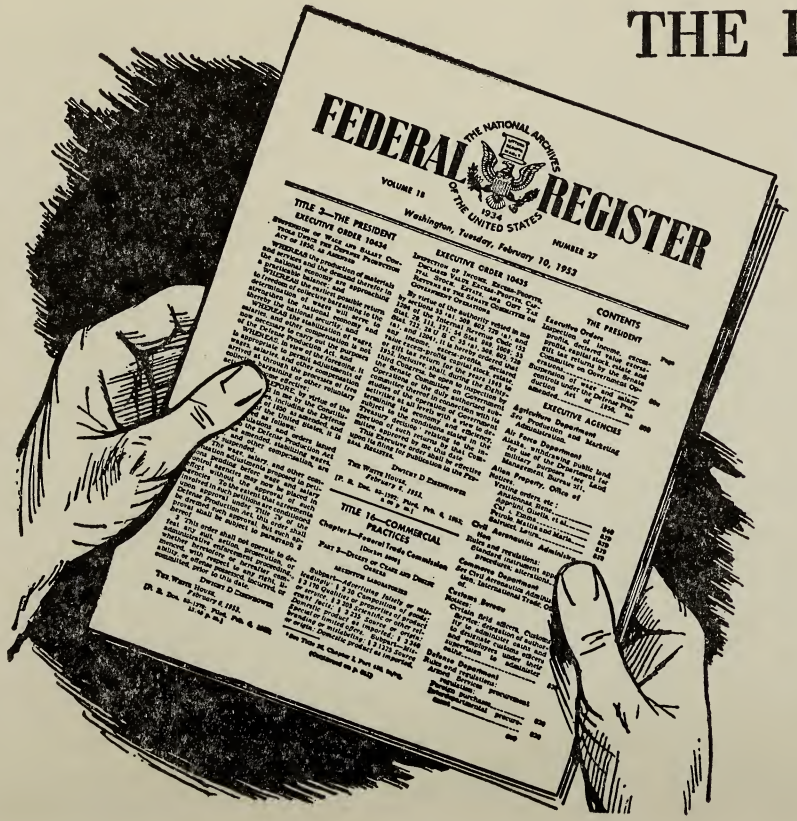
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U. S. GOVERNMENT PRINTING OFFICE: 1953





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D. D. N. J., F. D. C. 4001–4020 Issued October 1953

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4001–4020

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*
WASHINGTON, D. C., *October 20, 1953.*

NOV 13 1953
U. S. DEPARTMENT OF AGRICULTURE

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

4001. Misbranding of pentobarbital sodium capsules and amphetamine sulfate tablets. U. S. v. Warren Drug Stores (Warren Drug Co. and Warren's A & T Drug Co.), Guy O. Martin, Jess H. Baker, Rex D. Oehm, Ernest E. Warneke, and Louis A. Fitl. Pleas of nolo contendere by each defendant. Fine of $135, plus costs, against firm, $30 against Defendant Martin, $20 each against Defendants Baker and Oehm, and $10 each against Defendants Warneke and Fitl. (F. D. C. No. 33747. Sample Nos. 14971–L, 14974–L, 14976–L to 14978–L, incl., 14982–L, 14985–L, 14986–L, 15204–L.)

INFORMATION FILED: January 28, 1953, District of Nebraska, against the Warren Drug Stores, a partnership, trading and doing business as the Warren Drug Co., at 515 Court St., Beatrice, Nebr., and as Warren's A & T Drug Co., at 608 Court St., Beatrice, Nebr., and against Guy O. Martin, Jess H. Baker, and Rex D. Oehm, partners in the partnership, and Louis A. Fitl, a pharmacist, and Ernest E. Warneke, a clerk employed by the partnership.

NATURE OF CHARGE: On or about March 26 and April 7, 18, 20, 22, and 23, 1952, while quantities of *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were being held for sale at the Warren Drug Stores, after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded as follows: Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use; Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and, Section 502 (e) (2), a portion of the repackaged *amphetamine sulfate tablets* failed to bear a label containing the common or usual name of each active ingredient of the drug.

On or about April 26 and 27, 1952, while a number of *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were being held for sale at the Warren Drug Stores, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drugs being misbranded.

The partnership was charged in each of the 9 counts of the information with causing the acts of repacking and dispensing, and the individuals were joined as defendants in the several counts as follows: Guy O. Martin, counts 1, 2, and 6; Jess H. Baker, counts 3 and 4; Ernest E. Warneke, count 5; Louis A. Fitl, count 7; and Rex D. Oehm, counts 8 and 9.

DISPOSITION: February 10, 1953. Pleas of nolo contendere having been entered, the court imposed a fine of $135, plus costs, against the partnership, $30 against Defendant Martin, $20 each against Defendants Baker and Oehm, and $10 each against Defendants Warneke and Fitl.

4002. Misbranding of pentobarbital sodium capsules, Dexedrine Sulfate tablets, and capsules containing dextro-amphetamine sulfate plus minerals and vitamins. U. S. v. Paramount Drug Co. Plea of nolo contendere. Fine, $25. (F. D. C. No. 32701. Sample Nos. 20763–L, 20795–L, 21417–L to 21420–L, incl., 22265–L, 22267–L.)

INFORMATION FILED: March 31, 1953, Middle District of Alabama, against the Paramount Drug Co., Montgomery, Ala.

NATURE OF CHARGE: On or about February 6 and May 3 and 4, 1951, while a number of *pentobarbital sodium capsules* and *Dexedrine Sulfate tablets* were being held for sale at the Paramount Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded as follows: Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), a portion of the repackaged *Dexedrine Sulfate tablets* failed to bear a label containing the common or usual name of each active ingredient of the drug; and, Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use.

On January 7 and 9, 1953, while a number of *capsules containing dextro-amphetamine sulfate plus minerals and vitamins* were being held for sale at the Paramount Drug Co., after shipment in interstate commerce, the defendant caused a number of the capsules to be dispensed without a prescription from a practitioner licensed by law to administer such drug. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drug being misbranded.

DISPOSITION: March 31, 1953. The defendant having entered a plea of nolo contendere, the court fined it $25.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4003. Misbranding of pentobarbital sodium capsules. U. S. v. Roy C. Holcomb (Holcomb Drug Store), and Adolph T. Stava. Plea of nolo contendere by Defendant Holcomb and plea of guilty by Defendant Stava. Fine of $50, plus costs, against Defendant Holcomb and $50 against Defendant Stava. (F. D. C. No. 33748. Sample Nos. 16242–L, 16243–L.)

INFORMATION FILED: January 21, 1953, District of Nebraska, against Roy C. Holcomb, trading as the Holcomb Drug Store, Broken Bow, Nebr., and Adolph T. Stava, a pharmacist.

ALLEGED VIOLATION: On or about March 28 and 31, 1952, while a number of *pentobarbital sodium capsules* were being held for sale at the Holcomb Drug Store, after shipment in interstate commerce, the defendants caused a number of the capsules to be repacked and dispensed without a prescription, which acts resulted in the repackaged capsules being misbranded.

*See also Nos. 4001, 4002.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use.

DISPOSITION: April 3, 1953. A plea of nolo contendere having been entered by Defendant Holcomb and a plea of guilty by Defendant Stava, the court fined Defendant Holcomb $50, plus costs, and Defendant Stava $50.

4004. Misbranding of pentobarbital sodium capsules and amphetamine sulfate tablets. U. S. v. Jacob Marcus (Shawmut Pharmacy). Plea of guilty. Fine of $500 and sentence of 6 months in jail; jail sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 33798. Sample Nos. 6135–L to 6137–L, incl., 6140–L, 6187–L, 6192–L, 6194–L, 6277–L.)

INFORMATION FILED: February 5, 1953, District of Massachusetts, against Jacob Marcus, trading as the Shawmut Pharmacy, Boston, Mass.

ALLEGED VIOLATION: On October 29 and 31 and November 10, 12, and 13, 1951, while a number of *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were being held for sale at the Shawmut Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a physician's prescription, which acts resulted in the drugs so dispensed being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the dispensed drugs failed to bear adequate directions for use; and, Sections 502 (b) (1) and (2), the *pentobarbital sodium capsules* and a portion of the *amphetamine sulfate tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the *amphetamine sulfate tablets* failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the *amphetamine sulfate tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 18, 1953. The defendant having entered a plea of guilty, the court fined him $500 and sentenced him to serve 6 months in jail. The jail sentence was suspended, and the defendant was placed on probation for 2 years.

4005. Misbranding of pentobarbital sodium capsules and amphetamine sulfate tablets. U. S. v. Henry C. Haeberle (Haeberle's Pioneer Drug Store). Plea of guilty. Fine of $70, plus costs. (F. D. C. No. 33754. Sample Nos. 43992–L, 43998–L.)

INFORMATION FILED: January 30, 1953, District of Nebraska, against Henry C. Haeberle, trading as Haeberle's Pioneer Drug Store, Broken Bow, Nebr.

ALLEGED VIOLATION: On or about March 31, and April 8, 1952, while a number of *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were being held for sale at Haeberle's Pioneer Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *amphetamine sulfate tablets* failed to bear the common or usual name of each active ingredient of the tablets.

DISPOSITION: April 3, 1953. The defendant having entered a plea of guilty, the court fined him $70, plus costs.

4006. Misbranding of pentobarbital sodium capsules and dextro-amphetamine sulfate tablets. U. S. v. Eugene Fred Scott (Scott's Decatur Pharmacy). Plea of nolo contendere. Defendant fined $350 and place on probation for 2 years. (F. D. C. No. 34309. Sample Nos. 1747–L, 1755–L, 1757–L, 1760–L, 2003–L, 2008–L.)

INFORMATION FILED: April 17, 1953, Northern District of Georgia, against Eugene Fred Scott, trading as Scott's Decatur Pharmacy, Decatur, Ga.

ALLEGED VIOLATION: On or about December 13 and 24, 1951, and January 7, 8, and 14, 1952, while a number of *pentobarbital sodium capsules* and *dextro-amphetamine sulfate tablets* were being held for sale at Scott's Decatur Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), a portion of the repackaged *dextro-amphetamine sulfate tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and

the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: May 1, 1953. The defendant having entered a plea of nolo contendere, the court fined him $350 and placed him on probation for 2 years.

4007. Misbranding of pentobarbital sodium capsules and methamphetamine hydrochloride tablets. U. S. v. Thomas H. Nelson and Leonard G. Schatz. Pleas of guilty. Fine of $200, plus costs, against each defendant. (F. D. C. No. 32709. Sample Nos. 546–L, 547–L.)

INFORMATION FILED: April 15, 1952, Southern District of Indiana, against Thomas H. Nelson and Leonard G. Schatz, partners in the partnership of Uptown Drugs, Indianapolis, Ind.

ALLEGED VIOLATION: On or about July 30, 1951, while a number of *pentobarbital sodium capsules* and *methamphetamine hydrochloride tablets* were being held for sale at the Uptown Drugs, after shipment in interstate commerce, Defendant Nelson caused a number of the *pentobarbital sodium capsules* and Defendant Schatz caused a number of the *methamphetamine hydrochloride tablets* to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; Section 502 (f) (1), the repackaged drugs failed to bear labeling containing adeqaute directions for use; and Section 502 (b) (1), the repackaged *methamphetamine hydrochloride tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the repackaged *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: January 16, 1953. Pleas of guilty having been entered, the court fined each defendant $200, plus costs.

4008. Misbranding of methyltestosterone tablets, methamphetamine hydrochloride tablets, dextro-amphetamine sulfate tablets, and capsules containing a mixture of pentobarbital and aspirin. U. S. v. Frank B. Freeman. Plea of nolo contendere. Fine, $350. (F. D. C. No. 32737. Sample Nos. 15395–L, 15396–L, 15400–L, 15401–L, 15403–L, 15405–L, 15406–L.)

INFORMATION FILED: October 16, 1952, Eastern District of Oklahoma, against Frank B. Freeman, a partner in the partnership of the Steele Drug Co., Ardmore, Okla.

ALLEGED VIOLATION: On or about October 10, 12, and 15, 1951, while a number of *methyltestosterone tablets, methamphetamine hydrochloride tablets, dextro-*

amphetamine sulfate tablets, and *capsules containing a mixture of pentobarbital and aspirin* were being held for sale at the Steele Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the repackaged drugs failed to bear labeling containing adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *capsules containing a mixture of pentobarbital and aspirin* contained a chemical derivative of barbituric acid, namely, pentobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the labeling of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), a portion of the *methyltestosterone tablets* failed to bear a label containing the common or usual name of each active ingredient of the drug; and, Section 502 (f) (2), the repackaged *methamphetamine hydrochloride tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: December 22, 1952. A plea of nolo contendere having been entered by the defendant, the court fined him $350.

4009. Misbranding of sulfathiazole tablets. U. S. v. Manion Mitchell (Gilbert Drug Co.), and Harry E. Mitchell. Pleas of guilty. Fine of $50 against each defendant. (F. D. C. No. 33854. Sample Nos. 20904–L, 22169–L, 22198–L, 22210–L.)

INFORMATION FILED: February 17, 1953, Northern District of Alabama, against Manion Mitchell, trading as the Gilbert Drug Co., Athens, Ala., and Harry E. Mitchell, a pharmacist.

ALLEGED SHIPMENT: On or about November 7 and December 20, 1951, and January 10 and 11, 1952, while a number of *sulfathiazole tablets* were being held for sale at the Gilbert Drug Co., after shipment in interstate commerce, the defendants caused various quantities of the tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the repackaged tablets failed to bear a label containing the common or usual name of the drug; and, Sections 502 (f) (1) and (2), the labeling of the repackaged tablets failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: April 7, 1953. Pleas of guilty having been entered by the defendants, the court fined each defendant $50.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4010. Adulteration and misbranding of amphetamine sulfate tablets. U. S. v. 11 Bottles * * *. (F. D. C. No. 31380. Sample No. 11171–L.)

LIBEL FILED: July 23, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about the first quarter of 1950 by the International Pharmaceutical Laboratories, from Great Neck, N. Y.

PRODUCT: 11 unlabeled 1,000-tablet bottles of *amphetamine sulfate tablets.* Examination showed that each tablet contained not more than 8.6 milligrams of amphetamine sulfate. The product was represented by a representative of the shipper to be 10-milligram amphetamine sulfate tablets.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance, namely, 8.6-milligram *amphetamine sulfate tablets*, had been substituted for 10-milligram amphetamine sulfate tablets.

Misbranding, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (e) (1), the label of the article failed to bear the common or usual name of the article, namely, "*amphetamine sulfate tablets.*"

DISPOSITION: The Lipton Drug Sales Co., Cleveland, Ohio, claimant, filed an answer admitting that the drug was shipped unlabeled but denying that the drug was adulterated and misbranded, together with a set of interrogatories to be answered by the Government.

After the Government answered the interrogatories, it filed a motion for summary judgment. On November 20, 1951, the court granted the Government's motion, on the ground that there was no genuine issue on the material fact that the product was transported from New York to Ohio without being labeled and was therefore subject to seizure as a misbranded drug. On January 21, 1952, a decree was entered providing for the condemnation and destruction of the product.

4011. Adulteration of sulfadiazine tablets. U. S. v. 13 Bottles * * *. (F. D. C. No. 33275. Sample No. 37685–L.)

LIBEL FILED: June 3, 1952, Eastern District of New York.

ALLEGED SHIPMENT: On or about May 7, 1952, by the Berkeley Drug Co., from Boston, Mass.

PRODUCT: 13 1,000-tablet bottles of *sulfadiazine tablets* at Brooklyn, N. Y.

LABEL, IN PART: (Bottle) "1000 Sulfadiazine * * * (2-Sulfanilamidopyrimidine) Compressed Tablets (scored) 0.5 Gm. (7.7 Grains)."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sulfadiazine Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard. The standard provides that sulfadiazine tablets contain not less than 95 percent of the labeled amount of sulfadiazine, whereas the article contained not more than 77 percent of the labeled amount of sulfadiazine.

DISPOSITION: May 26, 1953. Default decree of condemnation and destruction.

4012. Adulteration and misbranding of vitamin tablets. U. S. v. 28 Bottles * * *. (F. D. C. No. 34575. Sample No. 17231-L.)

LIBEL FILED: February 2, 1953, Southern District of California.

ALLEGED SHIPMENT: On or about September 1 and October 25, 1950, and December 28, 1951, from Newark, N. J.

PRODUCT: 28 100-tablet bottles of *vitamin tablets* at Los Angeles, Calif. Analysis showed that the product contained 27 percent of the declared amount of vitamin B_1 (thiamine hydrochloride).

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 10 milligrams of thiamine hydrochloride (vitamin B_1) per tablet.

Misbranding, Section 502 (a), the label statement "Each Tablet Contains: * * * Thiamine Hydrochloride 10 Mg." was false and misleading as applied to an article which contained less than 10 milligrams of thiamine hydrochloride (vitamin B_1) per tablet.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 6, 1953. Decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4013. Misbranding of Ca-Ma-Sil Antacid Powder. U. S. v. 11 Cans * * *. (F. D. C. No. 31149. Sample No. 1510-L.)

LIBEL FILED: May 21, 1951, Middle District of Georgia.

ALLEGED SHIPMENT: On or about February 15, 1951, by the Ca-Ma-Sil Co., from Baltimore, Md.

PRODUCT: 11 cans of *Ca-Ma-Sil Antacid Powder* at Meigs, Ga.

LABEL, IN PART: "Ca-Ma-Sil Antacid Powder Net Weight 6 Oz. Contains: Magnesium Silicate * * * Diammonium Hydrogen Phosphate, Calcium Carbonate, Peppermint Oil, Aromatics and Saccharin."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in a leaflet and circular entitled "New Treatment For Peptic Ulcer and Hyperacidity" and in a brochure entitled "Improved Therapy for Duodenal and Gastric Ulcer," which accompanied the article, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for duodenal and gastric ulcer, whereas the article was not an adequate and effective treatment for such conditions.

DISPOSITION: June 29, 1951. Default decree of condemnation and destruction.

4014. Misbranding of Rumarid. U. S. v. 373 Bottles, etc. (F. D. C. No. 32222. Sample Nos. 29790-L, 29791-L.)

LIBEL FILED: December 10, 1951, Western District of Washington.

ALLEGED SHIPMENT: On or about October 3, 1951, by Stanley Drug Products, Inc., from Portland, Oreg.

*See also No. 4012.

PRODUCT: *Rumarid.* 373 100-tablet bottles and 219 250-tablet bottles, together with a number of leaflets headed "A New Formula" which were included in the carton containing each 100-tablet bottle, in the possession of the Bartell Drug Co., Seattle, Wash.

RESULTS OF INVESTIGATION: Displayed on the window of one of the retail stores of the consignee, at Seattle, Wash., was a circular placard headed "A New Relief from Pain! Rumarid." On display in this same store, together with unit cartons and bottles of the article, were a number of leaflets headed "New" and a large rectangular placard headed "Rumarid." These placards and leaflets were included in the shipment with the article. Attached to a stand in this store was a tear sheet from the Seattle Times headed "Pain Relief."

LABEL, IN PART: (Bottle and carton) "Rumarid * * * Each Tablet Contains: Acetylsalicylic Acid 3.5 grains, Caffeine .5 grain, Thiamine Chloride (B–1) 1 milligram, Ascorbic Acid 10 milligrams, Magnesium Salicylate 1.5 grains, Calcium Succinate 1 grain, Calcium Glutamate 1 grain."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Rumarid" and certain statements and designs in the accompanying labeling were false and misleading. The name "Rumarid" and the statements and designs represented and suggested that the article was capable of ridding the body of rheumatic conditions; that the article was a new and adequate and effective treatment for arthritis, rheumatism, neuritis, sciatica, and bursitis; that the United States Patent Office had issued a patent for *Rumarid;* that the article contained a new and effective ingredient called Renelon; that it contained as an ingredient calcium acetylsalicylate; and that caffeine, thiamine chloride, ascorbic acid, calcium succinate, and calcium glutamate are active ingredients to effect the claimed purposes of the article. The article was not capable of ridding the body of rheumatic conditions, and it was not a new and adequate and effective treatment for arthritis, rheumatism, neuritis, sciatica, and bursitis; the United States Patent Office had not issued a patent for *Rumarid;* Renelon is not the common or usual name of any known drug; the article did not contain calcium acetylsalicylate as an ingredient; and caffeine, thiamine chloride, calcium succinate, and calcium glutamate are not active ingredients to effect the claimed purposes of the article.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient since the ingredient declared as acetylsalicylic acid is not declared by its common or usual name, aspirin.

The article was misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: December 21, 1951. Stanley Drug Products, Inc., Portland, Oreg., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be relabeled under the supervision of the Federal Security Agency. The product was brought into compliance with the law by the relabeling of the bottles and the destruction of the cartons, leaflets, and other display material.

4015. Misbranding of Desert-Air Lamp. U. S. v. 74 Devices, etc. (F. D. C. No. 30924. Sample No. 10132–L.)

LIBEL FILED: April 16, 1951, Eastern District of Michigan; amended libel filed April 19, 1951.

ALLEGED SHIPMENT: On or about September 26, 1950, and February 27, 1951, by the Dal Corp., from Hollywood, Calif.

PRODUCT: 74 devices, known as *Desert-Air Lamps*, at Detroit, Mich., together with a number of placards entitled "Bring the Desert Into Your Home Desert-Air Lamps" and a number of folders entitled "America's Wonderlamp the amazing . . . dark-burning Desert-Air Lamp." Attached to each lamp was a tag entitled "Here's To Your Health Bring the Desert Into Your Home."

Examination showed that the lamp consisted of a parabolic reflector, with a central cone electric heating unit located in the center of the reflector.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the above-mentioned placards, folders, and tags accompanying the article, was false and misleading. The labeling represented and suggested that the article was effective to relieve bronchitis, head colds, hay fever, asthma, and all types of respiratory ailments, and that it was effective to make babies breathe more easily and sleep better, to relieve the stuffy feeling in the baby's nose, to relieve night coughing, and to improve the user's health. The article would not fulfill the promises of benefit stated and implied.

DISPOSITION: Lloyd H. Elrod, Detroit, Mich., the consignee and owner of the devices, and the Dal Corp., the shipper of the devices, filed answers denying that the labeling contained false and misleading statements. The Government subsequently served upon these parties a set of written interrogatories which were answered by the Dal Corp. Thereafter, Lloyd H. Elrod indicated that he was willing to enter into a consent decree of condemnation, but the Dal Corp. refused to admit the allegations of misbranding.

The case came on for trial before the court without a jury on May 12, 1953, and at its conclusion, the court ruled in favor of the Government. On June 9, 1953, the court entered its findings of fact and conclusions of law that the device was misbranded by reason of false and misleading statements in the labeling with respect to the efficacy of the devices.

In accordance with the findings and conclusions, the court entered a decree of condemnation on June 9, 1953, and ordered that the Government recover court costs, storage costs, and other proper expenses from the Dal Corp., and that the condemned devices be released under bond to Lloyd H. Elrod to be relabeled under the supervision of the Department of Health, Education, and Welfare.

4016. Misbranding of Magnetic Ray device. U. S. v. 9 Devices, etc. (F. D. C. No. 30796. Sample No. 13069–L.)

LIBEL FILED: March 6, 1951, District of Colorado; libel amended on or about September 21, 1951.

ALLEGED SHIPMENT: On or about January 4 and 23, 1951, by the Magnetic Ray Co., from Dallas, Tex.

PRODUCT: 9 *Magnetic Ray devices* at Denver, Colo., together with a number of leaflets entitled "Directions for Taking Magnetic Ray Treatments" and "This is a copy of a letter written by Frank B. Moran, M. D." and a number of booklets entitled "Magnetic Ray Treatment."

The device consisted essentially of a coil of wire enclosed in a covering of imitation leather and made in the form of a belt. Attached to the device was an electric cord which was to be plugged into an ordinary lighting current outlet.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklets and leaflets accompanying the device were false and misleading. The statements represented and suggested that the device was effective in the treatment of acid stomach, anemia, arthritis, asthma, affections

of the pelvic organs, Bright's disease, bronchial trouble, bladder trouble, bad circulation, catarrh, catarrhal deafness, constipation, diabetes, eczema, goiter, hay fever, heart disease, high and low blood pressure, headache, hemorrhoids, indigestion, insomnia, lumbago, nervousness, paralysis, painful menstruation, prostate, rheumatism, sciatica, sinus trouble, toxemia, tumors, varicose veins, and ulcers; and that it was effective to increase the elimination of poisons, greatly assisting in the removal of toxic conditions; to promote and equalize circulation of the blood, relieving congestion in every part of the body; to relieve pain and other distressing physical sensations; to produce marked relaxation and promote sound and refreshing sleep; to stimulate a normal functioning of the various glands and other organs of the body; to overcome fatigue which is a usual result of toxemia; to increase efficiency both physical and mental; to exert a revitalizing influence upon the sexual or procreative glands; and to clear the complexion.

DISPOSITION: E. J. Reynolds, Denver, Colo., claimant, filed a motion to strike certain allegations from the libel and a motion for dismissal of the libel, and on August 9, 1951, the court overruled these motions. The claimant filed an answer to the libel on August 11, 1951, and, thereafter, the Government served a number of written interrogatories upon the claimant which were answered.

On or about September 21, 1951, the libel was amended to charge that the device was misbranded not only when introduced into and while in interstate commerce but also while held for sale after shipment in interstate commerce. The Government filed at this time a motion for summary judgment which was argued before the court on November 2, 1951.

On April 16, 1952, the court granted the motion for summary judgment and entered a decree providing for condemnation of the devices, the delivery of 3 of the devices and certain labeling to the Food and Drug Administration, and the destruction of the remainder of the devices and labeling.

A notice of appeal to the Court of Appeals for the Tenth Circuit was filed by the claimant, and on July 16, 1952, pursuant to a stipulation by and between the parties, an order was entered directing the dismissal of the appeal.

4017. Misbranding of Oxydonor device. U. S. v. 5 Devices, etc. (F. D. C. No. 33287. Sample No. 37893–L.)

LIBEL FILED: June 25, 1952, Southern District of New York.

ALLEGED SHIPMENT: The devices were shipped on or about December 12, 1949, December 30, 1950, and January 30, 1951, by the B. J. Riley Mfg. Co., from Newark, N. J. A number of booklets relating to the devices were mailed at various times from Dr. H. Sanche & Co., Ltd., Montreal, Canada.

PRODUCT: 5 *Oxydonor devices*, together with various unassembled parts of the devices consisting of approximately 770 empty cylinders, 1,000 metal discs (ankle plates), 1,000 ankle plate slides, and 500 wire connectors, and a number of booklets entitled "Brief Directions for the use of Oxydonor" and leaflets entitled "Important Notice," at New York, N. Y., in the possession of the Hydrotonic Co. The leaflets had been printed locally.

The complete device consisted of a hollow metal cylinder filled with powdered ferric oxide, into one end of which was screwed a plug to which was attached a length of wire. In the case of some of the devices, there was attached to the other end of the wire a metal disc to which was attached also an elastic tape by means of which the disc could be held against the ankle. In the case of other devices, the wire from the plug was attached to two other wires, each of which was attached to a metal disc and elastic tape as described.

LABEL, IN PART: (Box containing device) "Oxydonor"; (engraved on cylinder) "Oxydonor * * * Manufactured by Dr. H. Sanche & Co., Montreal, Canada * * * Made in U. S. A."; (engraved on disc) "Dr. H. Sanche & Co. * * * Made in U. S. A."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklet and leaflet accompanying the devices were false and misleading since the statements represented and suggested that the device was effective in the cure and mitigation of all forms of diseases, whereas the device exerted no curative or therapeutic effect whatever.

Some typical statements contained in the labeling of the device to convey such representations and suggestions were as follows: (Engraved on cylinder) "Diaduction Rules Life," (on booklet) "Condensed Directions For The Proper Use of Oxydonor To cure all forms of Disease quickly, intangibly, pleasantly, infallibly, during sleep, or while awake; and to brace the Human System in all conditions, with Animation never before known, and not otherwise attained, whether in Disease or Debility, or in Fatigue, and in all Physical and Mental Ordeals. To Induce a Diaductive Cure of Disease," and (in leaflet) "* * * If an acute disease is to be treated, such as severe cold, severe pain, sprains, croup, etc., apply Oxydonor at once * * * In chronic diseases, apply Oxydonor."

DISPOSITION: August 19, 1952. Default decree of condemnation. The court ordered that a number of the devices and their parts, together with copies of the booklets and leaflets, be delivered to the Food and Drug Administration, and that the remainder of the devices and parts and booklets and leaflets be destroyed.

4018. Misbranding of Roller Relaxer device. U. S. v. 85 Devices * * *. (F. D. C. No. 34031. Sample No. 14048–L.)

LIBEL FILED: October 27, 1952, District of Colorado.

ALLEGED SHIPMENT: On or about August 18, 1952, by Post & Post, from Los Angeles, Calif.

PRODUCT: 85 *Roller Relaxer Devices* at Denver, Colo. Examination showed that the device consisted of 3 rubber balls mounted so that they would rotate on an axis between two wooden handles.

LABEL, IN PART: (Cardboard insert) "Relax the Entire Body with the Post Roller Relaxer * * * Easy-N-Quick-Beauty Stick."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the devices, namely, the cardboard insert, represented and suggested that use of the device would relax nerves and muscles and enable overweight persons to reduce. The statements were false and misleading since the device was not effective for such purposes.

DISPOSITION: December 16, 1952. Default decree of condemnation. The court ordered that the product be turned over to the Food and Drug Administration.

DRUGS FOR VETERINARY USE

4019. Misbranding of Airsac-Treat (powder and liquid). U. S. v. 9 Bags, etc. (F. D. C. No. 34445. Sample No. 38891–L.)

LIBEL FILED: December 17, 1952, Northern District of West Virginia.

ALLEGED SHIPMENT: On or about July 28 and August 18, 1952, by the Early Poultry Supply (Subsidiary of Airsac-Treat, Inc.), Broadway, Va.

PRODUCT: 9 31-ounce bags of *Airsac-Treat Powder* and 9 1-gallon bottles of *Airsac-Treat Liquid* at Moorfield, W. Va.

Examination showed that the powder consisted essentially of a mixture of baking soda and partially dried epsom salt and that the liquid consisted of an aqueous solution of sodium hypochlorite. When dissolved and diluted as directed in the labeling, the solution would contain approximately 0.9 percent sodium bicarbonate, 0.25 percent epsom salt, and 0.14 percent available chlorine.

LABEL, IN PART: (Bag) "Airsac-Treat Powder Mix this powder thoroughly with Airsac-Treat Liquid as indicated on label of bottle"; (bottle) "It's Here! Airsac-Treat * * * Active Ingredients: Magnesium sulfate (Epsom Salts), available Chlorine, Magnesium Hypochlorite, Magnesium Hydroxide and Sodium Sulfate (Glaubers Salts)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label designation "Airsac-Treat" and the following statements on the bottle label "A Treatment for Airsac Colds in Chickens & Turkeys * * * At first symptom of Airsac Colds in chickens or turkeys mix Airsac-Treat Solution into drinking water. Treat until all symptoms of Airsac Colds have disappeared" were false and misleading since the article was not an adequate and effective treatment for "Air-sac Disease" in poultry.

DISPOSITION: March 13, 1953. Default decree of condemnation and destruction.

4020. Misbranding of Master Liquid. U. S. v. 11 Jugs, etc. Default decree of condemnation and destruction entered. Motion filed by shipper to set aside decree; motion denied. (F. D. C. No. 34117. Sample No. 43874–L.)

LIBEL FILED: November 11, 1952, Northern District of Iowa.

ALLEGED SHIPMENT: On or about October 2 and November 7, 1952, by the Master Laboratories, from Omaha, Nebr.

PRODUCT: 11 5-gallon jugs and 14 1-gallon jugs of *Master Liquid* at Onawa, Iowa.

Analysis showed that the article contained the ingredients listed on the label, except that it contained no sodium bicarbonate but did contain sodium carbonate (sodium hydroxide and sodium bicarbonate cannot coexist in solution, as they react chemically).

LABEL, IN PART: (Jug) "Master Liquid * * * Ingredients: Sodium Thio-Sulphate; Beechwood Creosote; Guaiacol; Powdered Extract of Licorice; Sodium Hydroxide 9%; Sodium Bicarbonate; Betanapthol; Oil of Anise; Sodium Phenosulfonate; Solution of Potassium Arsenite; (Arsenic as Arsenous Oxide, 0.75%); Nicotinic Acid. Manufactured by Master Laboratories."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements appearing in the labeling were misleading: (Jug label) "Master Liquid For Old Hogs and Young Pigs * * * Estimate the largest amount of whole oats your hogs will eat in one day. For every three bushels of whole oats to be fed, mix 1 pint of Master Liquid * * * with 15 gallons of clean water * * *. To this solution add the whole oats and mix well by stirring. * * * Keep the prepared oats in feeding troughs at all times so hogs have free access to them. * * * Follow this practice for the first two weeks. The third week: Feed prepared oats in the morning and give other feeds during the remainder of the day. The fourth week: The animals can be put back on regular rations and thereafter fed prepared oats two or three days each week. On these days allow no other feed or they can be fed the preparation every morning and other

feed the the remainder of the day." These statements suggested and implied that the article was an effective remedy for diseases of swine, whereas it was not an effective remedy for such purposes.

Further misbranding, Section 502 (a), the representation on the label "Alkalinizes Slops composed of Oats, Barley or Grain Mixtures" was misleading since the labeling of the article failed to reveal the material fact in the light of such representation that such alkalinization was of no value or importance.

DISPOSITION: December 20, 1952. No claimant having appeared, judgment of condemnation and destruction was entered. On December 31, 1952, the Master Laboratories, the shipper, filed a motion to vacate the judgment. The motion was argued and was denied on January 26, 1953.

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[1] (4010, 4015, 4016) Seizure contested.
[2] (4020) Motion denied to vacate judgment.

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Warren Drug Stores:
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Warren's A & T Drug Co. *See* Warren Drug Stores.

[1] (4010, 4015, 4016) Seizure contested.
[2] (4020) Motion denied to vacate judgment.

U. S. GOVERNMENT PRINTING OFFICE: 1953

3rd

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

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4021–4040

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *November 25, 1953.*

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277915—53——1

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4021. Misbranding of acetylsalicylic acid tablets, ophthalmic ointment, potassium iodide tablets, and rhinitis tablets. U. S. v. 4 Cartoned Bottles, etc. (F. D. C. No. 34671. Sample Nos. 36592–L, 70132–L to 70136–L, incl.)

LIBEL FILED: February 18, 1953, Southern District of Ohio.

ALLEGED SHIPMENT: Between August 22 and December 30, 1952, by Eli Lilly & Co., from Indianapolis, Ind.

PRODUCT: 4 cartoned bottles of 1 grain *acetylsalicylic acid tablets*, 133 cartoned bottles of 5 grain *acetylsalicylic acid tablets*, 22 cartoned tubes of *ophthalmic ointment*, 34 bottles of *potassium iodide tablets*, and 4 bottles of *rhinitis tablets* at Dayton, Ohio.

LABEL, IN PART: (Bottle) "100 Tablets * * * A. S. A. (Acetylsalicylic Acid, Lilly) 1 gr. (0.065 Gm.) * * * Dose—1 tablet as directed by the physician" and "Tablets * * * A. S. A. (Acetylsalicylic Acid, Lilly) 5 grs. (0.325 Gm.) * * * Adult Dose—1 to 3 tablets as directed by the physician"; (tube) "⅛ Ounce Ophthalmic Ointment * * * Atropine Sulfate 1 percent To be used as directed by the physician"; (bottle) "100 * * * Enseals (Timed Disintegrating Tablets, Lilly) Potassium Iodide 5 grs. (0.325 Gm.) * * * Adult Dose—1 or 2 'Enseals' as directed by the physician. Indiscriminate use may be dangerous" and "1000 Tablets * * * Rhinitis Full Strength * * * Each tablet contains: Camphor_____ ½ gr. : 0.0325 Gm. Quinine Sulfate_____ ½ gr. : 0.0325 Gm. Ext. Belladonna Root_____ ⅛ gr. : 0.0035 Gm. (Total Alkaloids, 1/960 gr.) Camphor being volatile, the exact quantity cannot be guaranteed. Adult Dose—1 or 2 tablets as directed by the physician. Indiscriminate use may be dangerous."

NATURE OF CHARGE: *Acetylsalicylic acid tablets* (1 grain and 5 grains), *potassium iodide tablets*, and *rhinitis tablets*. Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use.

Rhinitis tablets. Misbranding, Section 502 (a), the label designation "Tablets * * * Rhinitis" was false and misleading since such designation represented and suggested that the article was an adequate and effective remedy for rhinitis, whereas it was not an adequate and effective remedy for rhinitis.

Ophthalmic ointment. Misbranding, Section 503 (b) (4), the article was a drug subject to Section 503 (b) (1) (B), and the label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: March 21, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4022. Misbranding of methyltestosterone tablets, thyroid tablets, dextro-amphetamine sulfate tablets, methamphetamine hydrochloride tablets, and tablets containing a mixture of phenobarbital and mannitol hexanitrate. U. S. v. Rice M. Reavis, Jr. Plea of nolo contendere. Fine, $350. (F. D. C. No. 33709. Sample Nos. 16316–L, 16317–L, 16321–L, 16323–L to 16325–L, incl., 16327–L.)

INFORMATION FILED: October 16, 1952, Eastern District of Oklahoma, against Rice M. Reavis, Jr., a partner in the partnership of the Reavis Drug Co., Ardmore, Okla.

*See also No. 4021.

ALLEGED VIOLATION: On or about October 10, 11, 12, and 15, 1951, while a number of *methyltestosterone tablets, thyroid tablets, dextro-amphetamine sulfate tablets, methamphetamine hydrochloride tablets,* and *tablets containing a mixture of phenobarbital and mannitol hexanitrate* were being held for sale at the Reavis Drug Co., after shipment in interstate commerce, one bottle of *thyroid tablets* was caused to be dispensed in the original bottle in which the tablets had been shipped in interstate commerce, without the prescription of a physician, and various quantities of the other drugs were caused to be repacked and dispensed without prescriptions, which acts resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the *thyroid tablets* failed to bear adequate directions for use. (The bottle in which the tablets had been shipped in interstate commerce bore no directions for use since it was exempt from such requirement by the statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of causing the dispensing of the drug without a physician's prescription caused the exemption to expire.)

Further misbranding, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), portions of the repackaged *methyltestosterone tablets* and *dextro-amphetamine sulfate tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *tablets containing a mixture of phenobarbital and mannitol hexanitrate* contained a chemical derivative of barbituric acid, namely, phenobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: December 22, 1952. The defendant having entered a plea of nolo contendere, the court fined him $350.

4023. Misbranding of sulfadiazine tablets, thyroid tablets, and methamphetamine hydrochloride tablets. U. S. v. Alvin H. Weinstein. Plea of nolo contendere. Fine, $75. (F. D. C. No. 34360. Sample Nos. 12081-L, 12726-L, 12729-L.)

INFORMATION FILED: April 23, 1953, Northern District of Ohio, against Alvin H. Weinstein, acting manager for the Schwartz Drug Co., Toledo, Ohio.

ALLEGED VIOLATION: On or about March 13 and 18, 1952, while a number of *sulfadiazine tablets, thyroid tablets,* and *methamphetamine hydrochloride tablets* were being held for sale at the Schwartz Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drugs to

be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *methamphetamine hydrochloride tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (e) (2), the repackaged *methamphetamine hydrochloride tablets* failed to bear a label containing the common or usual name of each active ingredient of the drug

Further misbranding, Section 502 (f) (2), the repackaged *sulfadiazine tablets* and *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: April 23, 1953. The defendant having entered a plea of nolo contendere, the court fined him $75.

4024. Misbranding of dextro-amphetamine sulfate tablets, amphetamine sulfate tablets, and capsules containing a mixture of Seconal Sodium and Amytal Sodium. U. S. v. Marshall W. Walton (Walton's Drug Store). Plea of guilty. Fine, $150. (F. D. C. No. 34349. Sample Nos. 31019–L, 34330–L, 34373–L, 34483–L, 34484–L, 34488–L.)

INFORMATION FILED: February 21, 1953, Western District of Missouri, against Marshall W. Walton, trading as Walton's Drug Store, Springfield, Mo.

ALLEGED VIOLATION: On or about March 17, 18, and 27, 1952, while a number of *dextro-amphetamine sulfate tablets*, *amphetamine sulfate tablets*, and *capsules containing a mixture of Seconal Sodium and Amytal Sodium* were being held for sale at Walton's Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *capsules containing a mixture of Seconal Sodium and Amytal Sodium* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *dextro-amphetamine sulfate tablets* and *amphetamine sulfate tablets* failed to bear labels containing the common or usual name of each active ingredient of the drugs.

DISPOSITION: March 4, 1953. The defendant having entered a plea of guilty, the court fined him $150.

4025. Misbranding of Solfera tablets. U. S. v. 63 Unlabeled Bottles, etc. (F. D. C. No. 34410. Sample No. 52320-L.)

LIBEL FILED: December 10, 1952, District of New Jersey.

INTERSTATE SHIPMENT: On or about June 10, 1952, from New York, N. Y.

PRODUCT: 63 unlabeled bottles and 385 labeled bottles of *Solfera tablets* in the possession of the Scientific Aids Co., Jersey City, N. J.

RESULTS OF INVESTIGATION: The tablets were shipped in a bulk container labeled, in part, "Tablets Ferrous Sulphate." They had been repacked in bottles, a portion of which were unlabeled and the remainder labeled. The tablets were advertised in various magazines, including the May 1952 issue of "Whisper," as follows: "Period Delayed * * * Don't Worry! Use Doctor's Prescription! Be relieved of this worry! Your Period Delay may be functional and this Doctor's Method may bring prompt relief! It is a Quality Preparation of Official Medical Drugs! Easy to take and No harmful after effects!"

LABEL, IN PART: (Bottle) "Solfera Tablets Directions: Take one tablet with water after each meal three times daily. CAUTION: Use only as directed. Contents: Ferrous Sulphate—Each Tablet contains 5 grains U. S. P. 50 Tablets Indicated for secondary Anemia when due to Iron Deficiency. Distributed By Scientific Aids Company, Inc."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended since its labeling bore no directions for use in treating delayed menstruation, which was the condition for which it was intended. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 23, 1953. Default decree of condemnation and destruction.

4026. Misbranding of Reeser's Vegetable Liver Pills. U. S. v. 20,000 Tablets, etc. (F. D. C. No. 33579. Sample No. 7936-L.)

LIBEL FILED: September 8, 1952, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 15, 1950, from Baltimore, Md.

PRODUCT: *Reeser's Vegetable Liver Pills.* 20,000 tablets and 3 dozen boxes, each box containing 20 tablets, and a number of loose labels at New Kensington, Pa., in the possession of the Bloom Drug Store.

RESULTS OF INVESTIGATION: The consignee had repacked the tablets into the boxes from the container in which the tablets were shipped and a number of labels were caused to be printed by the consignee.

LABEL, IN PART: (Bulk shipment) "Private Formula No. 7295 Powd Ext Belladonna Lvs 1/10 Gr (.00124 Grain Alkaloids.) Powd Ext Cascara Sag. Podophyllin Aloin"; (box) "Reeser's Vegetable Liver Pills * * * Bloom Drug Store 968 Fourth Avenue New Kensington, Pa."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements on the label of the article "* * * Liver Pills for sick headache, dizziness, biliousness, sluggish liver, nerve and blood disorders * * * they will exert a wonderful tonic effect in nervous ailments and blood disorders" were false and misleading since the article was not an adequate and effective treatment for the diseases, symptoms, and conditions suggested and implied.

Further misbranding, Section 502 (b) (1), the label of the article failed to bear the name and place of business of the manufacturer, packer, or distributor, since the name and address appearing on the label of the repackaged article, namely, "Bloom Drug Store, New Kensington, Pa.," were not those of the manufacturer and were not qualified by phraseology that revealed the connection which Bloom Drug Store had with the article; and Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient and the quantity of belladonna alkaloids contained in the article.

Further misbranding, Section 502 (f) (2), the labeling failed to bear adequate warnings against use of the article in those pathological conditions where its use may be dangerous to health, and against unsafe duration of administration, since its labeling failed to bear a warning against use when there is abdominal pain, nausea, vomiting, or other symptoms of appendicitis; the labeling failed to bear a warning to the effect that frequent or continued use, or use in accordance with the directions appearing upon the label, namely, "If one is taken each night or one every other night as indicated," may result in establishing dependence upon laxatives to move the bowels; and the labeling failed to bear a warning to the effect that if a skin rash appeared, use of the article should be discontinued.

The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: November 24, 1952. Default decree of condemnation and destruction.

4027. Misbranding of Mer-I-Col iron tonic. U. S. v. 60 Bottles, etc. (F. D. C. No. 33219. Sample No. 2295-L.)

LIBEL FILED: April 28, 1952, Southern District of Georgia.

ALLEGED SHIPMENT: On or about March 12, 1952, by the National Mer-I-Col Sales Co., from Columbus, Ohio.

PRODUCT: 60 1-pint bottles and 58 8-ounce bottles of *Mer-I-Col iron tonic* at Savannah, Ga.

RESULTS OF INVESTIGATION: In the March 14 and 21, 1952, issues of a newspaper circulated in the Savannah area, there appeared advertisements for the product. These advertisements were printed on instructions of, and from mats furnished by the National Mer-I-Col Sales Co.

LABEL, IN PART: "Mer-I-Col Iron Tonic Active Ingredients Iron and Ammonium Citrates, Gentian Root, Thiamine Hydrochloride and a trace of Copper Sulfate (Iron Catalyst). Directions One tablespoonful before each meal, three times a day."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of rheumatism, arthritis, neuritis, stomach ailments, weak kidneys, rheumatic pains, headaches, acids, toxins, bloating, weak back, lumbago, leg pains, lack of vitality and energy, poor appetite, nervousness, underweight, dizzy spells, indigestion, stomach gas, dyspepsia, intense pain in the stomach and chest, wild heart palpitation, fire-like feeling from the throat to the pit of the stomach, loss of weight, tissue, and strength, sour stomach, cramps, spitting up bits of half-digested food and hot, sour liquid, biliousness, sick headaches that last for

days, constipation, yellowish complexion, painful, heavy, bloated feeling in the lower stomach, worn-out feeling, sleeplessness, neuralgia, sharp pain over the kidneys, aching back, stiffness in the back and lower limbs, frequent rising at night, spots before the eyes, swelling of the ankles, feet, and lower limbs, puffs or dark circles under the eyes, atomic constipation, and spastic constipation, which were the conditions for which the article was intended. The article was misbranded in the above respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the labeling of the article, namely, clippings of a newspaper advertisement which accompanied the article, contained certain false and misleading statements. These statements represented and suggested that the article was an effective treatment for rheumatism, arthritis, neuritis, stomach ailments, weak kidneys, rheumatic pains, headaches, acids, toxins, bloating, weak back, lumbago, leg pains, lack of vitality and energy, poor appetite, nervousness, underweight, dizzy spells, indigestion, stomach gas, dyspepsia, intense pain in the stomach and chest, wild heart palpitation, fire-like feeling from the throat to the pit of the stomach, loss of weight, tissue, and strength, sour stomach, cramps, spitting up bits of half-digested food and hot, sour liquid, biliousness, sick headaches that last for days, constipation, yellowish complexion, painful, heavy, bloated feeling in the lower stomach, worn-out feeling, sleeplessness, neuralgia, sharp pain over the kidneys, aching back, stiffness in the back and lower limbs, frequent rising at night, spots before the eyes, swelling of the ankles, feet, and lower limbs, puffs or dark circles under the eyes, atomic constipation, and spastic constipation. The article was not an effective treatment for such conditions. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: June 17, 1952. Default decree of condemnation and destruction.

4028. Misbranding of Super Lipitrons vitamin and iron capsules. U. S. v. 28 Cases, etc. (F. D. C. No. 33566. Sample Nos. 15246–L, 15247–L.)

LIBEL FILED: September 5, 1952, District of Nebraska.

ALLEGED SHIPMENT: On or about November 1, 1951, from Detroit, Mich.

PRODUCT: *Super Lipitrons vitamin and iron capsules.* 28 cases, each containing 12,000 capsules in bulk, and an unknown number of 100-capsule bottles and 250-capsule bottles of the product and a number of loose labels, in the possession of Vitamin Industries, Inc., at Omaha, Nebr.; in addition, 101 100-capsule bottles and 25 250-capsule bottles of the product were at Omaha, Nebr., in the possession of Vitamin Stores, Inc.

RESULTS OF INVESTIGATION: The product was shipped in bulk, and after arrival at Omaha, a number of capsules were repackaged by Vitamin Industries, Inc., into 100-capsule and 250-capsule bottles bearing the Super Lipitrons label.

In advertisements in an Omaha newspaper, there appeared, on July 13 and August 3, 1952, over the name and address of Vitamin Stores, Inc., at Omaha, statements in which "Lipitrons" capsules were offered to provide extra vigor and extra energy for persons over 35, and for those who are suffering from tiredness, weakness, and nervousness, or for those who are lacking in strength and vigor, because of deficiencies of vitamins B_1 and B_2, iron, and vitamin C, and for those who are now past their youth and have been blaming their tired, weak feeling on "just getting old"; to overcome deficiencies that help drag one

down and down; to reveal a whole new world of buoyant energy, vitality, and strength when the signs of advancing age are due to lack of thiamine, riboflavin, niacinamide, and vitamin C; to build new, red blood; to attack the true, basic causes of the tired feeling, poor appetite, loss of weight and strength, insomnia or sleeplessness, and other conditions of deficiencies in one's nutritional intake that may be responsible for one's condition; and to enable one to really begin to enjoy life again and to know the joy of feeling one's level best.

LABEL, IN PART: (Bottles) "Super Lipitrons Improved B Complex Vitamin C Iron Vitamin Industries Incorporated 1511 Davenport St., Omaha 2, Nebr. * * * Each Capsule Contains: Vitamin B_1---- 15 mgm. Vitamin B_2---- 6 mgm. Vitamin C---- 50 mgm. Niacinamide---- 30 mgm. Calcium Pantothenate---- 3 mgm. Vitamin B_6---- 0.5 mgm. Liver Concentrate---- 30 mgm. Choline Dihydrogen Citrate---- 20 mgm. Inositol---- 20 mgm. Iron as Ferrous Gluconate---- 30 mgm. Folic Acid---- 0.1 mgm. Vitamin B_{12} USP (Crystalline)---- 3 mcg. and dl-Methionine---- 20 mgm."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article in bulk and in the bottles failed to bear adequate directions for use for which it was intended. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 17, 1952. Vitamin Industries, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency. The product was relabeled.

4029. Misbranding of Drown Radio Therapeutic Instrument. U. S. v. Ruth B. Drown (Drown Laboratories). Motion for dismissal of information denied. Plea of not guilty. Tried to court and jury. Verdict of guilty. Fine, $1,000. Judgment affirmed on appeal to Court of Appeals for Ninth Circuit. Petition for certiorari denied by Supreme Court. (F. D. C. No. 29440. Sample No. 60624-K.)

INFORMATION FILED: January 29, 1951, Southern District of California, against Ruth B. Drown, trading as Drown Laboratories, Los Angeles, Calif.

ALLEGED SHIPMENT: On or about October 28, 1948, from the State of California into the State of Illinois, of 1 *Drown Radio Therapeutic Instrument.*

The device was accompanied by certain labeling consisting of circulars entitled "The Drown Radio Diagnostic Therapeutic Photographic Instruments"; leaflets entitled "Drown Atlas"; a chart dated March 7, 1949, and entitled "The Drown Radio Therapy . . . Home Vibra Ray Diagnosis"; a chart dated February 7, 1949, and entitled "Drown Laboratory of Radio Therapy . . . Treatment Rates"; a letter signed "Dr. R. B. Drown" replying to a letter dated March 9, 1949, from Mr. Rice to Dr. Drown; a chart dated July 15, 1949, and entitled "Drown Laboratory of Radio Therapy . . . Treatment Rates"; and a letter dated August 3, 1949, from Dr. Ruth B. Drown to Mr. E. C. Rice. The device was accompanied also by 6 ampuls of drugs to be used unopened in conjunction with the operation of the device.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the device were false and misleading since the device, when used with or without the unopened ampuls of drugs accompanying it, would not provide the therapeutic benefits stated and implied. The

statements suggested that the device would eliminate a lump or lumps in the breast and prevent cancer therefrom; that it would treat disease; that it would direct the body energy to the diseased area, resulting in the formation of healthy cells; that it would step up the vibrations in the area of the diseased organ, bringing in new cells and causing the diseased cells, which cannot live in the higher rate of vibration, to fall away; that it would bring about cell division; that it would be efficacious in treating any part of the body and in treating, selectively, the area into which it was "tuned"; that it surpassed any other known method of therapy; that it would be efficacious in the treatment of kidney and bladder complications, adhesions, tipped uterus, extra kidney, painful urination, calcium deposit in the ureter and urethra, inflammation and streptococcus in the urethra and in the pyloric end of the stomach, and bladder; that it would be efficacious in the treatment of cirrhosis and carcinoma of the right kidney and interstitial tissue; that it would be efficacious in the treatment of low function of the left suprarenal gland, pancreas, prostate, and testicles of a six-year-old boy; that it would be efficacious in the treatment of fibrous adhesions in the brain and meningeal tissue, affecting the eleventh dorsal; that it would be efficacious in the treatment of contracted brain sinus, cystic fluid in the brain and madulla, heart trouble of many years' standing, head pains and noises, "explosions" in right ear when falling asleep, constipation, pains in the lower back, and enlargement and trauma of left ventricle of the heart; that it would be efficacious in the treatment of calcium deposit in the right kidney, cystic fluid in the right kidney and ureter, aftereffects of scarlet fever, septicemia in the left mastoid, headaches, streptococcus, abscesses, loss of speech and memory, inability to digest food, vomiting of bile, frequent passing into coma, abscesses draining in an arm, an elbow, and the back of a hand, inability to lift the arm, and abscesses in the brain, left medulla, and left ear; that it would be efficacious in the treatment of low functioning of most of the glands, affections of the glands, female organs, male organs, and blood, head colds, sore throat, cold in the lungs, and affections of the left and right bronchials and lungs; that it would be efficacious in the treatment of worry, fear, and nervousness; and that it would be efficacious in the treatment of cold with an achy feeling, cold with a hot and cold feeling, affections of the lymphatics of the right breast, and affections of the kidney, gallbladder, colon, liver, ovary, small intestine, bile duct, uterus, and rectum.

Further misbranding, Section 502 (a), the labeling of the device suggested that another Drown device, a diagnostic instrument, would tune into the body and its various organs, glands, systems, and parts so as to measure their function and detect the presence of disease, record "impinged" nerves, count the cells in the blood, analyze urine, and ascertain blood pressure and body temperature; that the diagnostic device would furnish a complete and scientifically accurate blueprint of the body and uncover many obscure conditions; and that it would employ the body's energy (that is, the electromagnetic force generated by the combination of minerals and fluids in the body and the total life force—an invisible light ray) in the diagnosis of disease and in the selection of remedies for disease. The diagnostic device was incapable of accomplishing such results.

Further misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use in the treatment of any of the conditions for which it was suggested in its labeling since the labeling failed to specify the frequency, duration, time, method, or manner of application or usage of the device or drugs in the treatment of such conditions.

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DISPOSITION: On April 2, 1951, the defendant filed a motion to dismiss the information, and on April 27, 1951, the court denied this motion. On September 11, 1951, the case came on for trial upon the defendant's plea of not guilty. The trial was had before a jury and was concluded with a verdict of guilty on September 24, 1951. On October 22, 1951, the court fined the defendant $1,000.

An appeal was taken by the defendant to the United States Court of Appeals for the Ninth Circuit, and on September 10, 1952, the following opinion was handed down by that court:

ORR, *Circuit Judge:* "The appellant, Dr. Drown, is a chiropractor who does business in Hollywood, California, under the name of Drown Laboratories. Appellant manufactures certain photographic, therapeutic and diagnostic instruments of her own design which she uses in her practice. She sold one of these instruments to a Mr. Rice, resident of Blue Island, Illinois, for which she was charged with selling a device that was misbranded, in violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. § 301 et seq., by reason of claims in its labeling which were allegedly false and misleading both with respect to the particular instrument sold to Rice and with respect to another instrument also designed by the appellant.[1]

"Fantastic therapeutic and diagnostic qualities are claimed by appellant for her instruments in their labeling. The Drown Radio Therapeutic Instrument, the device whose sale resulted in her arrest, is represented as capable of eliminating a lump in the breast and preventing cancer therefrom; as efficacious in treating kidney and bladder complications, tipped uterus, extra kidney, painful urination, streptococcus in the urethra and the pyloric end of the stomach, and bladder, cirrhosis and carcinoma of the right kidney, low function of the left suprarenal gland, pancreas, fibrous adhesions in the brain and meningeal tissue, brain sinus, cystic fluid in the brain and medulla, heart trouble, head pains and noises, explosions in right ear while falling asleep, constipation, pains in the lower back, abscesses, loss of speech and memory, worry, fear and nervousness, conditions of the colon and liver. The device is further represented as effective in the treatment of many other ailments; and it is asserted that the contraption 'far surpasses any other known method of . . . therapy.'[2] Another larger instrument advertised for sale by appellant is represented as having not only the therapeutic qualities attributed to the smaller instrument but also extraordinary diagnostic properties.[3]

"Appellant's instruments employ no commercial electricity; they are represented as employing the patient's own body energy in diagnosis, remedy selection and treatment.[4] The instruments are based upon appellant's theory of vibration: '. . . under the laws of vibration, each individual has a rate of vibration peculiar to himself. In addition, each organ, gland, etc., in the body has its own rate of vibration. Likewise various diseases all vibrate to specific rates (slower or coarser than the normal body rates and more akin to earth vibrations).'[5] Appellant asserts that this body energy may be directed through her instrument back to the diseased part of the body at the same vibration rate previously found in diagnosis to be appropriate for the treatment of that particular area. 'This steps up the vibrations in that particular area . . . and the diseased cells will automatically fall away, since disease cannot live in the higher rate of vibration.'[6] Both diagnosis and treatment, the

[1] The one count information was based upon 21 U. S. C. §§ 321 (h), 331 (a), 333 (a), 352 (a), and 352 (f) (1).

[2] Most of these claims are made in the circular entitled "The Drown Radio Therapeutic Photographic Instruments."

[3] This instrument is represented as capable of measuring the function of the various parts of the body, detecting the presence of disease, and taking blood count, urinalysis, blood pressure and temperature; all accomplished merely by tuning in on the vibrations of the body.

[4] "By body energy we mean that electro-magnetic force which is generated by the combination of the minerals and the fluids of the body, as well as the total life force, which is an invisible light ray just past the white light in the spectrum . . . ."

[5] See footnote 2.

[6] See footnote 2.

appellant claims, can be accomplished either directly or with the patient absent entirely from the physical proximity of the instrument. When the patient is present, two pieces of metal attached by wires to the instrument are placed upon the body, a drop of the patient's blood is placed in the device, and unopened ampuls of chemicals are sometimes placed on the face of the instrument. When the patient is not present, diagnosis and treatment may still take place, a piece of blotting paper with a second drop of the patient's blood being clamped between the two pieces of metal.

"Two of the Government's witnesses, one a physicist and the other a radio engineer, testified that they had taken the instruments apart and found that the devices consist of a wire with two dissimilar metals as electrodes on either end; that in effect they operate in a manner similar to a chemical battery; that when the circuit is completed by placing the electrodes in contact with the human body or any other conductor of electricity a minute flow of current is generated and may be measured by the micrometer in the device; that the devices are incapable of measuring, detecting, or transmitting electromagnetic energy of any kind.

"Six eminent medical witnesses testified for the Government. Each is an authority in a specialized area of medicine. These expert witnesses expressed the unanimous belief that appellant's instruments are useless for diagnosis or treatment of any human ailment. Dr. Carpender testified concerning actual tests conducted by the appellant at the University of Chicago, which tended to support the conclusions of the Government's medical witnesses.[7]

I. THE INTERSTATE TRANSACTION

"Rice, concerned about a lump in his wife's breast, had been advised by a business friend, while temporarily in Los Angeles, to contact appellant. On phoning appellant's place of business in Hollywood, Rice was informed that she was then in Chicago. When Rice returned to his home in a suburb of Chicago he made an appointment with appellant for an examination of his wife. Mrs. Rice had been previously examined by her family doctor who had suspected a possible cancer and suggested an immediate biopsy. Appellant concluded from her examination of Mrs. Rice on April 23, 1948, by means of one of her instruments that the lump was not a cancer but was caused by a fungus that had spread through her digestive system into the liver.[8] Appellant at that time gave Mr. and Mrs. Rice a copy of a pamphlet describing the alleged qualities of her devices[9] and recommended treatments with the Drown Radio Therapeutic Instrument by a Dr. John, who practiced in Chicago. Mrs. Rice commenced taking the treatments and appellant advised their continuation upon re-examination of Mrs. Rice in September, 1948. The treatments continued until, on October 28, 1948, Rice went to the Drown Laboratories in Hollywood and personally purchased the device in question. Rice returned to Blue Island, Illinois, and his wife used the instrument to treat the lump in her breast.

"Appellant first contends that the purchase of the Drown Radio Therapeutic Instrument by Rice at the Drown Laboratories in Hollywood was a wholly intrastate transaction and, therefore, not within the scope of the Federal Food, Drug, and Cosmetic Act. It is alleged that transportation in interstate commerce or an obligation to so transport on the part of the appellant is an essential element of the offense; that since any transportation in interstate commerce was brought about by the purchaser, the seller, Dr. Drown, was not criminally responsible.

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[7] Dr. Carpender was present at tests carried on by the appellant at the University of Chicago on December 31, 1949. The appellant attempted to diagnose the physical condition of three persons from samples of their blood which had been obtained by the University and dried on small pieces of filter paper identified only by number. The diagnoses of Dr. Drown, obtained by means of one of her instruments, differed radically from the actual physical condition of the persons in question as it appeared in the records obtained by the University in preparation for the tests.

[8] Testimony was to the effect that at the time of the trial Mrs. Rice's condition was malignant, and she was physically unable to make the trip to Los Angeles for the purpose of testifying.

[9] See footnote 2.

"Appellant relies upon a number of cases dealing with the power of a state to tax goods moving in interstate commerce.[10] They are not in point since the question in such cases does not concern the power of Congress to regulate, but whether a particular exercise of state power in view of its nature and operation must be deemed in conflict with the federal power. The power of a state to tax is not necessarily inconsistent with the power of Congress to regulate under the Commerce Clause.[11] Minnesota v. Blasius, 290 U. S. 1 (1933); Stafford v. Wallace, 258 U. S. 495 (1922); Bacon v. Illinois, 227 U. S. 504 (1913); Swift & Co. v. United States, 196 U. S. 375 (1905).

"Appellant argues that federal power over interstate commerce is limited to transportation. We do not agree. The power of Congress to regulate interstate commerce may be exercised to the utmost extent, and acknowledges no limitations other than those that are prescribed by the Constitution. Gibbons v. Ogden, 9 Wheat. 1 (1824). Where goods are purchased in one state for transportation to another, the commerce includes the purchase quite as much as it does the transportation. Currin v. Wallace, 306 U. S. 1 (1939); Lemke v. Farmers Grain Co., 258 U. S. 50 (1922); Dahnke-Walker Milling Co. v. Bondurant, 257 U. S. 282 (1921). The place where title technically passes is not significant. Santa Cruz Fruit Packing Co. v. N. L. R. B., 303 U. S. 453 (1938); N. L. R. B. v. Lavaur, 115 F. 2d 105 (1st Cir. 1940), cert. denied, 312 U. S. 682. Even if the sale to Rice with knowledge that he intended to take the device to Illinois be not considered part of the stream or flow of commerce, a 'flow of commerce' is not essential to the federal power to regulate. The instances in which the metaphor 'stream of commerce' has been used are but particular, and not exclusive, illustrations of the protective power which Congress may exercise. Santa Cruz Fruit Packing Co. v. N. L. R. B., *supra*; N. L. R. B. v. Jones & Laughlin Steel Corp., 301 U. S. 1 (1937). The power to regulate wholly intrastate activities because of their relation to or effect upon interstate commerce is now established. Mandeville Island Farms, Inc. v. American Crystal Sugar Co., 334 U. S. 219 (1948); Wickard v. Filburn, 317 U. S. 111 (1942); United States v. Wrightwood Dairy Co., 315 U. S. 110 (1942); United States v. Darby, 312 U. S. 100 (1941); N. L. R. B. v. Jones & Laughlin Steel Corp., *supra*; Stafford v. Wallace, *supra*. The power of Congress to regulate the sale of a drug within one state where transportation to another state by either the purchaser or seller is contemplated by the parties therefore cannot be successfully disputed.

"Having determined that Congress had the power to regulate the sale in question, we next consider whether Congress intended to exercise that power. Appellant asserts that transportation in interstate commerce or an obligation to so transport on the part of the seller is an essential element to criminal responsibility. The statute prohibits 'The introduction or *delivery for introduction into interstate commerce* of any food, drug, or cosmetic that is adulterated or misbranded.' 21 U. S. C. A. § 331 (a) (Our emphasis). Appellant's interpretation fails to give meaning to the entire wording of the statute. Referring to this Act, the Supreme Court of the United States has said: 'The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.' United States v. Dotterweich, 320 U. S. 277, 280 (1943). See United States v. Walsh, 331 U. S. 432, 434 (1947). Having in mind the broad purpose of the Act, protection of the public health, we believe that Congress intended to prohibit the delivery of a misbranded device by a seller to the purchaser where the seller has knowledge that the purchaser intends to introduce the device into interstate commerce by taking it into another state. The Tenth Circuit adopted this interpretation of the statute in a recent case, United States v. Sanders, ... F. 2d . . . . . (May 7, 1952), where a seller was held to have violated an injunction by selling misbranded drugs intrastate knowing that the purchasers

[10] For example: Superior Oil Co. v. Mississippi, 280 U. S. 390 (1930); United Fuel Gas Co. v. Hallanan, 257 U. S. 277 (1921); McCluskey v. Marysville & Northern Railway Co., 243 U. S. 36 (1917); Ware & Leland v. Mobile County, 209 U. S. 405 (1908); New York, ex rel. Hatch v. Reardon, 204 U. S. 152 (1907); Coe v. Errol, 116 U. S. 517 (1886); Utah Power & Light v. Pfost, 52 F. 2d 226 (Idaho 1931).

[11] United States Constitution, Art. I, § 8.

intended to take the drugs out of the state. Such an interpretation gives reasonable meaning to each word of the statutory prohibition. A comparable interpretation has been given to similar language in the Fair Labor Standards Act. See Tobin v. Grant, 79 F. Supp. 975 (N. D. Cal. 1948).

"The appellant endeavors to distinguish the Sanders case by pointing out that the defendant there was engaged regularly in an interstate business of selling. The Sanders case, however, does not turn on the nature of the seller's business, but rather upon whether the seller had knowledge that the misbranded drugs would be taken out of the state. The Act does not require a business; it prohibits *each* sale in violation of the statutory prohibition. 21 U. S. C. A. § 331 (a).

"The evidence was sufficient to support a finding that the sale to Rice constituted 'delivery for introduction into interstate commerce.' Both by recommending that Mrs. Rice receive treatments by the Drown Radio Therapeutic Instrument and through the descriptive circular that was given to Mr. and Mrs. Rice in Chicago, the appellant stimulated interest in her device and led Mr. Rice to believe that her instrument 'far surpasses any other known method of diagnosis or therapy.' The appellant knew the device was to be used to treat a lump in Mrs. Rice's breast, and it is obvious that she contemplated that Mr. Rice would take the device back to his Illinois home. The invoice of sale states that the instrument was sold to 'Mr. Edgar Rice, 13005 Greenwood Ave., *Blue Island, Illinois*.'

II. THE INFORMATION

"Appellant asserts that the information upon which she was convicted is defective in a number of ways.

"First, it is said that the information fails to allege a crime. The cases which the appellant cites [12] merely set forth various applications of the general rule in testing the sufficiency of an indictment or information. As this court stated in Woolley v. United States, 97 F. 2d 258, 261 (9th Cir. 1938), cert. denied, 305 U. S. 614: 'It is not necessary that an indictment set forth a myriad of detail, or that it satisfy every objection which human ingenuity can devise. It is enough if it charges every essential element of the offense and at the same time apprises the accused of the charge against him in such a manner that he can prepare his defense without being taken by surprise, and that he have the assurance that he will be protected against another prosecution for the same offense.' See Hagner v. United States, 285 U. S. 427, 431 (1932). Appellant contends that the Government failed to plead sufficient facts as to the nature of the device and the method and manner of interstate shipment to inform her sufficiently of the nature of the charge and protect her from subsequent prosecution for the same offense. The appellant was apprised of the nature of the charge to the extent that she entered into a stipulation as to facts. The information described the alleged offense in considerably greater detail than the form of indictment appearing in the Appendix of Forms following the Federal Rules of Criminal Procedure, 18 U. S. C. A. See Form 11. The information specifies the name, model number and serial number of the particular device sold to Rice, thereby precluding a second prosecution for its sale.[13] The test of an information is not whether it could have been made more definite and certain in any way. Hagner v. United States, *supra*. Appellant could have sought a bill of particulars to clarify any uncertainty. Fed. R. Crim. P. 7 (f).

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[12] For example:
United States v. Simmons, 96 U. S. 306 (1878);
Fontana v. United States, 262 F. 283 (8th Cir. 1919);
United States v. Albert Steinfeld & Co., 209 F. 904 (Ariz. 1913);
United States v. Burns, 54 F. 351 (C. C. D. W. V. 1893);
United States v. Nelson, 52 F. 646 (Minn. 1892).

[13] The information alleges:
"That displayed upon said device was certain labeling which consisted of the following printed and graphic matter:

DROWN RADIO THERAPEUTIC INSTRUMENT
Patent Applied For
Manufactured by
DROWN LABORATORIES
LOS ANGELES
Model No. 98M Serial No. 10264817"

"Appellant next asserts, with respect to violation of the requirement of a label containing adequate instructions for use imposed by 21 U. S. C. A. § 352(f)(1), that she should have been exempted under the terms of the proviso granting exemption for any drug or device where the Administrator finds that directions for use are not necessary for the protection of public health.[14] She argues that the use of her instruments 'could not possibly harm any human being.' While the instruments may be harmless in themselves, their danger lies in the possibility that 'ignorant and gullible persons are likely to rely upon them instead of seeking professional advice for conditions they are represented to relieve or prevent.' United States v. Kordel, 164 F. 2d 913, 916 (7th Cir. 1948), affirmed, 335 U. S. 345; see Ewing v. Mytinger & Casselberry, Inc., 339 U. S. 594, 600 (1950). In this broader sense appellant's instruments cannot be considered harmless. Thus, even if the proviso were to be considered mandatory in certain situations, see Justice Rutledge concurring, United States v. Sullivan, 332 U. S. 689, 704 (1948), the appellant has not made a sufficient showing that the requirements of 21 U. S. C. A. § 351 (f) (1) are 'not necessary for the protection of the public health' as regards her instruments.

"Complaint is made that the information is based upon irrelevant and immaterial matter insofar as it charges that certain circulars and letters not in existence at the time of the sale in question constitute part of the instrument's labeling.[15] Most of the claims concerning the qualities of appellant's instruments are made in the circular actually given to Rice at the time of the sale. It was stipulated that all of the circulars and letters were part of the labeling of the device. Further, the Supreme Court of the United States has held that 'labeling' in the statutory sense is not confined to materials given simultaneously to the purchaser with the product, but rather that materials sent to the purchaser subsequent to the sale may constitute part of the 'labeling' where one integrated transaction is involved.[16] Kordel v. United States, 335 U. S. 345 (1948). In the present case the subsequent materials gave instructions as to use of the instrument and contained diagnoses of Mrs. Rice's condition. In the light of the integrated nature of the whole transaction these subsequent materials constituted part of the whole transaction.

"It is further asserted that reference in the information to a second instrument which was not sold to Rice was prejudicial. Appellant claims she cannot determine whether she is charged with misbranding the instrument sold to Rice, another instrument, or both instruments. We find that the information clearly alleges that *the device sold to Rice was misbranded* in that its labeling contained false and misleading therapeutic claims about that device and false and misleading diagnostic claims about a second device. The applicable statute states that a drug or device shall be deemed misbranded 'if its labeling is false or misleading *in any particular*.' 21 U. S. C. A. § 352 (a) (our emphasis). The statute thus does not confine the definition of misbranding to statements concerning the labeled device itself. We believe that the interpretive regulation of the Federal Security Administrator construing this

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[14] "§ 352. Misbranded drugs and devices. A drug or device shall be deemed to be misbranded—

"(f) Directions for use and warnings on label. Unless its labeling bears (1) adequate directions for use; . . . Provided, that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the administrator shall promulgate regulations exempting such drug or device from such requirement."

[15] The information described the device's labeling as follows:

"That accompanying said device was certain additional labeling relating to said device namely, circulars entitled 'The Drown Radio Diagnostic Therapeutic Photographic Instruments'; leaflets entitled 'Drown Atlas'; a chart dated March 7, 1949, and entitled 'The Drown Radio Therapy . . . Home Vibra Ray Diagnosis'; a chart dated 2/7/49 and entitled 'Drown Laboratory of Radio Therapy . . . Treatment Rates'; a letter signed Dr. R. B. Drown replying to a letter dated March 9, 1949, from Mr. Rice to Dr. Drown; a chart dated 7/15/49 and entitled 'Drown Laboratory of Radio Therapy . . . Treatment Rates'; and a letter dated August 3, 1949, from Dr. Ruth B. Drown to Mr. E. C. Rice: . . ." [Our emphasis.]

[16] "§ 321. Definitions; generally. For the purposes of this chapter—

'(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' "

language to include representations on the labeling of one device with respect to another device constitutes a reasonable construction of the statute.[17]

III. OTHER CONTENTIONS

"A motion for an instructed verdict filed by the appellant at the close of the Government's case was denied by the district court. No similar motion was made at the close of all the evidence. Appellant now seeks to assert that the denial of her motion for an instructed verdict constituted error. However, appellant by offering evidence after her motion was denied and not subsequently renewing that motion, waived the motion so that it need not be considered on appeal. Mosca v. United States, 174 F. 2d 448 (9th Cir. 1949) and cases cited at 451; see Gaunt v. United States, 184 F. 2d 284, 290 (1st Cir. 1950), cert. denied, 340 U. S. 917.

"On October 22, 1951, 28 days after the verdict had been returned by the jury, appellant moved for permission to file motions for a new trial and in arrest of judgment. She contends that denial of these motions by the district court constituted error because she had substituted counsel and he was unable to familiarize himself with the trial record at an earlier date. A motion for a new trial based on any grounds other than newly discovered evidence, as well as a motion in arrest of judgment, must be filed within five days after verdict or within such further time as the court may fix during that five day period. Fed. R. Crim. P. 33 and 34. Grounds for extending this five day period are expressly limited. Fed. R. Crim. P. 45 (b). The district court therefore lacked jurisdiction to grant the appellant's motions. Marion v. United States, 171 F. 2d 185 (9th Cir. 1948), cert. denied, 337 U. S. 944; see United States v. Smith, 331 U. S. 469, 473–475 (1947). The dictum in Abbot v. Brown, 241 U. S. 606, 609 (1916), relied upon by the appellant, is not in point since it involves a situation where a motion for new trial was granted in violation of a mere regulation of practice followed by a particular district court prior to the adoption of the Federal Rules of Criminal Procedure, 18 U. S. C. A.

"A number of other contentions are made by the appellant in her brief. However, we do not find them sufficiently substantial to warrant discussion.

"Judgment affirmed."

A petition for a writ of certiorari subsequently was filed with the United States Supreme Court, and on January 19, 1953, this petition was denied.

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[17] 21 C. F. R. (1949 Ed.) Sec. 1.101 (p. 12): "Drugs and devices; labeling misbranding—

(a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic." [Our emphasis.]

4030. Misbranding of Le Joi device. U. S. v. 160 Devices, etc. (F. D. C. No. 33126. Sample No. 17220–L.)

LIBEL FILED: May 15, 1952, Southern District of California.

ALLEGED SHIPMENT: On or about April 15, 1952, by the Propenex Co., from Minneapolis, Minn.

PRODUCT: 160 *Le Joi devices* at Hollywood, Calif., each of which was packed in a plastic case containing a leaflet entitled "Instructions Le Joi." Additional leaflets entitled "New Horizons," which were used by the consignee in promoting the sale of the device, were caused to be printed by the consignee in Los Angeles, Calif., from copies of a similar leaflet originally obtained from the Propenex Co.

Examination showed that the device consisted of a thin rubber tube with a locking attachment at each end.

NATURE OF CHARGE: The libel alleged that the device was misbranded while held for sale after shipment in interstate commerce within the meaning of

Section 502 (a), in that certain statements in the leaflet entitled "New Horizons" accompanying the device were false and misleading. The statements represented and suggested that use of the device was effective in improving the sexual capacities of older men by enlarging and reinforcing the sexual organ. The device was not effective for such purpose, and it would not fulfill the promises of benefit made for it.

The libel alleged also that if the leaflet entitled "New Horizons" was not part of the labeling of the device, then the device was misbranded when introduced into and while in interstate commerce within the meaning of Section 502 (f) (1), in that its labeling failed to state the purposes and conditions for which the device was intended, namely, to improve the sexual capacities of older men by enlarging and reinforcing the sexual organ.

DISPOSITION: June 13, 1952. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4031. Adulteration and misbranding of Vio-Ferronate tablets. U. S. v. Rowell Laboratories, Inc. Plea of nolo contendere. Fine, $350. (F. D. C. No. 34351. Sample No. 48581-L.)

INFORMATION FILED: March 19, 1953, District of Minnesota, against Rowell Laboratories, Inc., Baudette, Minn.

ALLEGED SHIPMENT: On or about February 7, 1952, from the State of Minnesota into the State of North Dakota.

LABEL, IN PART: (Bottle) "Coated Tablets Vio-Ferronate Ferrous Gluconate with Liver and Vitamin B-12 * * * Rowell Laboratories Division of Burbot Liver Products Co. Baudette, Minnesota."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet of the article purported and was represented to contain 3 milligrams of thiamine hydrochloride, 1 milligram of pyridoxine, and 30 milligrams of vitamin C, whereas each tablet contained less than 3 milligrams of thiamine hydrochloride, less than 1 milligram of pyridoxine, and less than 30 milligrams of vitamin C.

Misbranding, Section 502 (a), the label statements displayed upon the bottles were false and misleading in that the statements represented and suggested that each tablet of the article contained 3 milligrams of thiamine hydrochloride, 1 milligram of pyridoxine, and 30 milligrams of vitamin C (ascorbic acid), whereas each tablet contained less than 3 milligrams of thiamine hydrochloride, less than 1 milligram of pyridoxine, and less than 30 milligrams of vitamin C (ascorbic acid).

DISPOSITION: May 20, 1953. The defendant having entered a plea of nolo contendere, the court fined it $350.

4032. Adulteration and misbranding of gum karaya. U. S. v. 75 Drums * * *. (F. D. C. No. 33513. Sample No. 54058-L.)

LIBEL FILED: September 3, 1952, Northern District of Illinois.

ALLEGED SHIPMENT: On or about July 28, 1952, by Dodwell & Co., Ltd., from Newark, N. J.

PRODUCT: 75 300-pound drums of *gum karaya* at Franklin Park, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (b), the product was represented to be "Gum Karaya," a drug, the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the standard set forth in such compendium since it contained more than 3 percent of bark and foreign and organic material and in a solution of the material (1 to 100), Millon's Reagent produced a yellow precipitate instead of a white precipitate as specified in the standard.

Misbranding, Section 502 (a), the label statement "Gum Karaya N. F." was false and misleading as applied to a product which failed to comply with the specifications in the National Formulary for gum karaya.

DISPOSITION: September 25, 1952. The shipper, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

On July 23, 1953, an amended decree was entered which provided for the relabeling of the product to indicate that it was not National Formulary gum karaya and to indicate the manner in which it differed from the National Formulary product.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4033. Misbranding of Kordolin tablets. U. S. v. 1,960 Bottles, etc. (F. D. C. No. 33242. Sample No. 23486–L.)

LIBEL FILED: May 7, 1952, District of New Jersey.

ALLEGED SHIPMENT: On or about April 3, 7, and 8, 1952, by the Kordol Corp., of America, from New York, N. Y.

PRODUCT: 1,960 100-tablet bottles and 864 50-tablet bottles of *Kordolin tablets* at Jersey City, N. J.

LABEL, IN PART: (Bottle) "Kordolin Tablets * * * Active Ingredients per tablet * Acket Acetphenetidin 2 gr. Calcium Succinate Caffeine Vitamin B_1 1 m. * Acket is Kordol Corporation of America's Brand Name of Salicylamide."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the bottle label and the retail package carton, contained prominently displayed statements arranged to represent and suggest that the article was an adequate and effective treatment for arthritis, rheumatism, sciatica, bursitis, and neuritis, which statements were misleading since the article was not an adequate and effective treatment for such conditions; and the statement on the bottle labels and retail package cartons, namely, "Active Ingredients * * * Calcium Succinate Caffeine Vitamin B_1," was misleading since calcium succinate, caffeine, and vitamin B_1 were not active ingredients of the article for the purpose for which it was offered.

Further misbranding, Section 502 (c), the information required by Section 502 (e) (2) to appear on the label, namely, the common or usual name of each active ingredient, was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, and devices in the labeling) and in such terms as to render it likely to be read and understood

*See also Nos. 4021, 4026, 4027, 4029–4032.

by the ordinary individual under customary conditions of purchase and use since the coined term "Acket" had been used for the ingredient salicylamide, as explained in a footnote, and the ingredients, calcium succinate, caffeine, and vitamin B_1, which were not active for the purposes for which the article was offered, appeared in such fashion as not to distinguish them from the active ingredients.

DISPOSITION: The Kordol Corp. of America appeared as claimant and filed an answer denying the allegations of the libel. On September 8, 1952, a set of written interrogatories was served upon the claimant by the Government. Thereafter, a motion was filed by the Government for an order striking the claimant's pleadings and for the entry of a default decree of condemnation upon the ground that the claimant failed to respond to the interrogatories within the time provided by the Federal Rules of Civil Procedure.

On April 10, 1953, the court granted the Government's motion, and in accordance therewith, it entered a decree providing for the condemnation and destruction of the product.

4034. Misbranding of Kon-trol-R. U. S. v. 30 Dozen Bottles, etc. (F. D. C. No. 34449. Sample No. 56927–L.)

LIBEL FILED: December 24, 1952, Southern District of Ohio.

ALLEGED SHIPMENT: On or about May 28, 1952, by the Kon-trol-R Co. of America, from Indianapolis, Ind.

PRODUCT: 24 dozen ½-pint bottles and 6 dozen 1-pint bottles of *Kon-trol-R* at Cincinnati, Ohio, together with a number of circulars entitled "Kon-trol-R For Your Figure." Examination showed that the product was mint-flavored cider vinegar.

LABEL, IN PART: "* * * Kon-trol-R For Your Figure * * * A Special Blend of Pure Apple Juice Processed for Optimum Acidity, Mint Flavored."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements on the label of the article and in the above-mentioned circulars, namely, "Kon-trol-R For Your Figure A Pleasant Aid to The Easiest System for Weight Control * * * A Simple Weight Controlling System," were false and misleading. The statements represented and suggested that the article was effective to bring about a loss of body weight, whereas it was not effective for such purpose.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: February 4, 1953. Default decree of condemnation and destruction.

4035. Misbranding of Aspergum. U. S. v. 48 Cartons * * *. (F. D. C. No. 33562. Sample No. 37284–L.)

LIBEL FILED: August 29, 1952, Southern District of New York.

ALLEGED SHIPMENT: On or about July 15, 1952, by White Laboratories, Inc., from Kenilworth, N. J.

PRODUCT: 48 cartons, each containing 1 dozen boxes, of *Aspergum* at New York, N. Y.

LABEL, IN PART: (Display carton) "Fast Relief for 'Sore Throat' Aspergum Aspirin In pleasantly-flavored Chewing Gum"; (box) "16 Tablets Aspergum Active Ingredient: Aspirin."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Fast Relief For 'Sore Throat'" borne on the display carton was false and misleading since it represented and suggested that the article was an adequate and effective treatment for sore throat, whereas it was not an adequate and effective treatment for that condition.

DISPOSITION: January 12, 1953. Default decree of condemnation. The court ordered that the product be delivered to a charitable institution for its use and not for sale.

4036. Misbranding of honey. U. S. v. 11 Cases, etc. (F. D. C. No. 33953. Sample Nos. 33824–L to 33827–L, incl.)

LIBEL FILED: October 24, 1952, Western District of Michigan.

ALLEGED SHIPMENT: On or about April 29, July 3, and September 11, 1952, by the Sun Fed Honey Co., from Sarasota, Fla.

PRODUCT: 11 cases, each containing 24 1-pound jars, and 3 cases, each containing 6 5-pound jars, of *honey* at Grand Rapids, Mich., together with a number of leaflets entitled "Honey Facts."

LABEL, IN PART: (Jar) "Sun Fed * * * Honey * * * Packed By Shangri-La Grove, Bee Ridge, Florida."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in the above-mentioned leaflet which accompanied the article, were false and misleading. The statements represented and suggested that honey supplies minerals, by means of which it acts as a "buffer between the acids of the body"; that it is health-giving, exerts a restorative action in elderly people, constitutes a protective food, and helps prevent acidosis; that, with milk, it effects longevity, enables weak and sickly children to recuperate and gain health, and builds up anemic and undernourished children, enabling them to attain higher mental ratings; that it is effective in heart affections, diabetes, insomnia, jaundice, chronic dysentery, swellings caused by heart and kidney ailments, and other diseases, osteomyelitis of large bones, gastric and intestinal ulcers, and bed wetting; that it will raise the calcium level and lower the phosphorus level of the blood; that it will sustain life and health indefinitely; that it prevents acidosis, rickets, scurvy, and other "decomposition" diseases; that it will kill germs of tuberculosis; that it is a healer for the membrane of the mouth, throat, and stomach; and that it is an antiseptic. The article did not supply a significant portion of minerals; it was not effective in the treatment of the diseases and conditions stated and implied; and it would not fulfill the promises of benefit made for it.

DISPOSITION: December 10, 1952. Default decree of condemnation. The court ordered that the product be delivered to a charitable institution for its use and not for sale and that the leaflets be destroyed.

4037. Misbranding of Silver-King Airborne Bacteria Control Unit. U. S. v. 2 Cartons, etc. (F. D. C. No. 33584. Sample No. 53143–L.)

LIBEL FILED: On or about September 17, 1952, Western District of Missouri.

Alleged Shipment: On or about November 7, 1951, by Thompson & Sons, Inc., from Lyons, Ill.

Product: 2 cartons, each containing 1 device labeled, in part, "Silver-King Airborne Bacteria Control Unit" and 1 3-ounce bottle of a drug labeled, in part, "Silver-King Triethylene Glycol Air Purification Grade" at Springfield, Mo., together with a number of accompanying booklets entitled "Silver-King Health Unit" and "Silver-King a complete combination of the uses for the health and beauty of the modern home."

The device consisted of a rectangular metal box so arranged that when triethylene glycol liquid was added, the box plugged into the house electric line, and a source of moving air provided (such as from the exhaust pipe of a Silver-King vacuum cleaner), warm triethylene glycol vapor was blown out into the room.

Nature of Charge: Misbranding, Section 502 (a), certain statements in the accompanying booklets were false and misleading. The statements represented and suggested that the device and the drug would provide an adequate and effective treatment for preventing colds, serious infections of the ears, nose, throat, and lungs, respiratory disease, tuberculosis, influenza, airborne disease, streptococcus infections, pneumonia, diseases of the nose, throat, and lungs, sore throat, bronchitis, sinusitis, middle ear disease, mastoiditis, la grippe, tonsilitis, rheumatic fever, abscessed ears, infections of wounds, childbirth infection, mumps, diphtheria, German measles, contagious diseases, bone infection, scarlet fever, erysipelas, and meningitis. The device and the drug would not provide an adequate and effective treatment for such diseases and conditions.

Disposition: November 1952. No claimant having appeared and the court having found that the device and the drug were misbranded as alleged in the libel, judgment was entered ordering that the device and the drug be delivered to the Federal Security Agency.

4038. Misbranding of Germaster device. U. S. v. 49 Devices, etc. (F. D. C. No. 33305. Sample No. 33727–L.)

Libel Filed: June 20, 1952, Northern District of Illinois.

Alleged Shipment: On or about June 9, 1951, by Lee Products Co., Inc., from Cleveland, Ohio.

Product: 49 *Germaster devices* and various accessories for use with the devices, including small, graduated cups with pouring lip, filters in a cellophane bag, directions for the mechanical operation of the device, and 4-ounce bottles of a colorless liquid, at Chicago, Ill., together with a sales manual entitled "Germaster The New Way to Say 'Germ Destruction with Glycol'."

The device consisted of a hollow plastic chamber containing a pad saturated with a solution composed of 50 percent triethylene glycol, 1 percent dimethylbenzyl ammonium chloride, and 49 percent water. A stubby, hollow cylinder projecting from the cover was provided for the entry of air, and long slots were in the body for the exit of the air. The device containing the saturated pad was to be attached to the exhaust end of a tanktype vacuum cleaner and air blown over the saturated pad and out into the room.

Nature of Charge: Misbranding, Section 502 (a), the name of the device and certain statements on the labels and in the above-mentioned sales manual ac-

companying the device were false and misleading. The name and the statements represented and suggested that use of the device was effective to rid the air of disease organisms and to prevent colds, mumps, influenza, whooping cough, polio, measles, scarlet fever, tuberculosis, and all airborne diseases. The device was not effective for such purposes.

DISPOSITION: June 30, 1953. Lee Products Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the device be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

4039. Misbranding of Pur Ozone Generator device. U. S. v. 10 Devices, etc. (F. D. C. No. 34122. Sample No. 19641–L.)

LIBEL FILED: November 12, 1952, District of North Dakota.

ALLEGED SHIPMENT: On or about September 19, 1952, by the Purozone Co., from Brea, Calif.

PRODUCT: 10 *Pur Ozone Generator devices* at Harvey, N. Dak., in the possession of H. C. Wagner, trading as the Purozone Co., together with a number of pamphlets entitled "Ozone Therapy by O. M. Justice, M. D." and "Bulletin No. 11 Ozone The Breath of Life" and a number of books entitled "Ozone God's Gift to Humanity No. 2 Lecture" and "Ozone God's Gift to Humanity No. 3 Lecture." The pamphlets entitled "Bulletin No. 11 Ozone The Breath of Life" had been printed locally for the consignee, and the other literature was shipped to the consignee by Dr. J. E. Effenberg, of Calozone, Inc., from Turlock, Calif.

The device consisted essentially of glass tubes that would glow and cause the formation of ozone in the surrounding air when the electrical attachments were connected with a suitable electric current. The consignee had assembled and labeled the devices with a metal plate.

LABEL, IN PART: (Metal plate) "Pur Ozone Registered Ozone Generator 110–120 Volts 10–40 Watts A. C. Purozone Company H. C. Wagner—Harvey, N. D."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned pamphlets and books accompanying the device were false and misleading. The statements represented and suggested that the device would assist health, prevent disease, and act as a specific in many diseases; and that it would be effective for adenitis, swelling of the breasts, angina pectoris, alopecia, falling of the hair, arthritis, asthma, arteriosclerosis, backache, biliousness, bronchitis, bursitis, colitis, colds, sore chest, constipation, dandruff, deafness, erysipelas, earache, eczema, high blood pressure, indigestion, jaundice, leucorrhea, mumps, nervousness, pleurisy, prostate trouble, pneumonia, pelvic disturbances, psoriasis, quinsy, sore throat, rheumatism, rectal disturbances, sleeplessness, sinus trouble, tuberculosis, varicose veins, wrinkles, infections and diseases of body cavities and passages, chlorosis, anemia, nervous prostration, chronic nasopharyngeal catarrh, whooping cough (pertussis), diphtheria, scarlet fever, pernicious anemia, cardiovascular and renal diseases, insomnia, hay fever, dyspepsia, headaches, inactive liver and kidneys, syphilis, rheumatisms of gonococcal origin, destruction of microbic diseases in human beings, fistula, influenza, osteomyelitis, "and many other ailments." The device was not capable of fulfilling the promises of bene-

fit made for it, and it would not be effective for the diseases and conditions stated and implied. The device was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 8, 1953. Default decree of condemnation. The court ordered that the generator or transformer of the device be turned over to the Department of Physics of the North Dakota State College and that the remainder of the device be destroyed.

4040. Misbranding of Calozone (also known as Vitozone) device. U. S. v. 3 Devices, etc. (F. D. C. No. 34164. Sample No. 2256–L.)

LIBEL FILED: December 16, 1952, Southern District of Florida.

ALLEGED SHIPMENT: About May 1952, John I. Crowder, Artesia, Fla., transported 1 device from the State of California to Artesia, Fla. Subsequently 2 more devices were shipped to John I. Crowder from the State of California.

PRODUCT: 1 device known alternatively as "Calozone" and "Vitozone" and a booklet entitled "Ozone Therapy by O. M. Justice, M. D.," at Artesia, Fla., and 1 device at Merritt Island, Fla., and 1 at Cocoa, Fla.

Examination showed that the device consisted essentially of a group of tubes, which, when activated by an electric current, fluoresced with production of ozone in the surrounding air.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the device, namely, the above-mentioned booklet, contained statements which were false and misleading. These statements represented and suggested that the device would prevent disease and act as a specific in many diseases, and that it was effective in the treatment of adenitis, swelling of the breasts, angina pectoris, alopecia, falling of the hair, arthritis, asthma, arteriosclerosis, backache, biliousness, bronchitis, bursitis, colitis, colds, sore chest, constipation, dandruff, deafness, erysipelas, earache, eczema, high blood pressure, indigestion, jaundice, leucorrhea, mumps, nervousness, pleurisy, prostate trouble, pneumonia, pelvic disturbances, psoriasis, quinsy, sore throat, rheumatism, rectal disturbances, sleeplessness, sinus trouble, tuberculosis, varicose veins, and wrinkles. The device was not effective for such purposes, and it was not effective in the treatment of such conditions.

DISPOSITION: January 22 and February 12, 1953. No claim having been made for the device located at Artesia, Fla., which was the only device seized, judgment of condemnation was entered. The court ordered that the device be delivered to the Food and Drug Administration for experimental use.

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[1] (4029) Prosecution contested. Contains opinion of the court.

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